Årsberetning

Annual Report

2004/2005

MEDICO
INDUSTRIEN

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Årsberetning | *Annual Report*

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Indholdsfortegnelse

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Forord

Medicoindustrien står overfor betydelige udfordringer. Virksomheder flytter løntung produktion til udlandet for at være konkurrencedygtige. Udenlandske virksomheder samler deres salgskontorer i nordiske enheder, og det offentlige udnytter sin købermagt ved at gå sammen i større indkøbsenheder.

Den udvikling betyder, at vi skal tænke nyt. Kun gennem virksomhedernes udvikling af nye produkter kan vi fastholde en betydelig medicoindustri i Danmark. Nye ideer og koncepter opstår typisk ved interaktion imellem virksomheder, behandlere, forskere og brugere inden for sundhedsvæsenet. Medicoindustrien har derfor sat fokus på samspillet mellem industri, sygehuse og universiteter. Det har vi gjort i MedicoFremtid, hvor vi har samlet de fagligt stærkeste kræfter i Danmark indenfor medicoteknologi, og det vil vi gøre i det innovationscenter, som vi opretter i 2005. Vi skal hjælpe nye forretningsidéer fra hospitaler og vidensmiljøer ud i erhvervslivet. Ingen kan gøre det bedre end Medicoindustrien på grund af vores medlemskreds, kontakten til det offentlige og vores helt særlige branchespecifikke faglige viden.

Sundhedsvæsenet er under økonomisk pres. Reaktionen er større indkøbsenheder med krav om lavere priser. Distributørerne mærker dette prispres meget tydeligt. Det er derfor vigtigere end nogensinde, at distributørerne tydeliggør, hvorfor det ikke kun er et produkt, sygehusene og kommunerne køber, men viden, uddannelse og service. Det offentlige må ikke tro, at man kan købe alle dele og kun betale for den ene.

Besparelser på sygehusene har bevirket, at nogle sygehuse genbruger medicinske engangsartikler. Det satte Medicoindustrien fokus på ved en høring i 2004. Den dagsorden, der er sat, vil række ind over indeværende og de følgende år.

Der kan opnås store besparelser hos det offentlige og i virksomhederne gennem elektronisk samhandel. Medicoindustrien og Amtsrådsforeningen gennemførte i 2004 et stort e-handelsprojekt, som har gjort parterne i stand til at køre med fuldt integreret elektronisk handel i et hidtil uset omfang.

Branchens og Medicoindustriens udfordringer får læserne et dybere indblik i på de følgende sider.

2004 blev et meget travlt år i Medicoindustrien. Vi er glade for den store opbakning fra medlemmerne. Det er et mål for os at have aktive medlemmer, og det er derfor med særlig glæde, at vi har kunnet konstatere, at 91% af medlemmerne har været aktive i organisationen i årets løb.

Tak for indsatsen!

Foreword

Medicoindustrien is facing challenges of magnitude. Companies are moving labour-intensive production abroad in order to remain competitive. Foreign companies are combining their sales offices into Nordic entities, and public purchasers are optimising their buying power by joining forces in large purchasing units.

These trends compel us to think innovatively at all times. There is only one way to maintain a vital medical device industry in Denmark and that is to develop new products. New ideas and concepts are often forged by the interaction of companies, treatment providers, researchers and users in the healthcare sector, the reason for Medicoindustrien's emphasis on cooperation between industry, hospitals and universities. This was our blueprint for MedicoFuture, where we gathered the strongest medical technology professionals in Denmark, and it is also our plan for the innovation centre we are setting up in 2005. We are going to help move new business ideas from hospitals and knowledge centres into the industry pipeline. No one can do this better than Medicoindustrien on the basis of our membership, contact with the public sector and specialised knowledge specific to the industry.

The public healthcare system is under heavy economic pressure, and their response is larger purchasing units and a demand for lower prices. Distributors can clearly feel the pressure on prices. Thus it is more important than ever for distributors to bring home the message that hospitals and local authorities are not just buying a product, but know-how, training and service as well. The public sector must not harbour the illusion that they can buy all the parts and pay for only one.

Budget cuts have led some hospitals to reuse disposable medical devices. Medicoindustrien focused on the practice by holding a hearing in 2004. The agenda that was set will extend throughout this year and several to follow.

The public sector and the industry can achieve significant savings through e-commerce. In 2004 Medicoindustrien and the Danish Regions carried through an extensive e-commerce project that allows the parties to operate fully integrated electronic business to an extent unknown previously.

Readers will be able to gain greater insight into the challenges facing the industry and Medicoindustrien in the following pages.

2004 was a very busy year for Medicoindustrien. The whole-hearted support of members is gratifying. One of our goals is to have an active membership, and thus it was particularly rewarding to see that 91% of members took an active part in the organisation during the year.

Thank you for your contribution!

MOGENS PEDERSEN
Formand
Chairman

DITTE NØRGAARD-ANDERSEN
Direktør
Director General

Medicoindustriens idégrundlag

Eksistensgrundlag

Medicoindustrien er brancheorganisationen for virksomheder, der i Danmark udvikler, producerer, sælger eller på anden vis har interesse i CE-mærket medicinsk udstyr. Medicoindustrien dækker branchens behov for:

Opinionspåvirkning

- af danske politikere, myndigheder, sundhedssektoren og andre beslutningstagere
- af internationale myndigheder – via EUCOMED
- af love og direktiver

Formidling af information

- vedr. love, direktiver, standarder og øvrige krav og deres fortolkning
- vedr. danske og internationale udviklingstrends og ændringer i branchevilkår

Erfaringsudveksling

- mellem medlemmerne om fælles problemstillinger m.v.

Uddannelse

- inden for branchespecifikke områder, der ikke i forvejen udbydes

Kompetencegrundlag

For at dække behovet vedrørende **opinionspåvirkning**, skal Medicoindustrien kunne:

- producere pålidelige branchespecifikke statistikker og analyser
- opbygge og vedligeholde kommunikation med beslutningstagere, presse og øvrige interessentgrupper
- bearbejde prioriterede interesseområder
- fortolke og formidle love og regler
- påvirke uddannelsessystemet til fordel for branchen

For at dække behovet for **formidling** skal Medicoindustrien kunne:

- indsamle, registrere og kommunikere branchespecifik viden i bearbejdet form, herunder bidrage med skøn vedrørende udviklingstrends m.v.

For at dække behovet for **erfaringsudveksling** skal Medico-industrien kunne:

- organisere møder og udvalgsvirksomhed

Medicoindustrien's Strategic business concept

Basic Objectives

Medicoindustrien is the trade organisation for companies in Denmark which develop, manufacture, sell or otherwise take an interest in CE-marked medical devices. Medicoindustrien meets the needs of the medical device industry in respect of:

Opinion shaping

- by influencing Danish politicians, authorities, the healthcare sector and other decision-makers
- with supranational official bodies/agencies - through EUCOMED
- in legislative matters - acts and directives

Communication of information

- regarding enacted laws, directives, standards and other official requirements and their interpretation
- on Danish and international healthcare trends and changes in the business conditions of the industry

Exchange of Experience

- among members about issues of common interest

Education and training

- within areas of specific interest to the industry not already offered by others

Basic Competencies

In order to meet the need for **opinion shaping**, Medicoindustrien must be able to:

- prepare reliable statistical and analytical material specific to the industry
- build and maintain channels of communication with decision-makers, the press and other stakeholders
- work at influencing prioritised spheres of interest
- interpret and communicate the contents of acts and legal rules
- influence the educational system for the benefit of the industry

In order to meet current **communication** needs, Medicoindustrien must:

- compile, record and communicate in adapted form knowledge specific to the industry, including estimates of the trend of future developments

For at dække behovet for **uddannelse** skal Medicoindustrien kunne:

- definere, udvikle, markedsføre og afvikle branchespecifikke kurser

Positioneringsgrundlag

Medicoindustrien vil i sine omgivelser være kendt for at være:

- en fagligt velfunderet og troværdig samarbejdspartner/ sparringspartner med en professionel fremtræden
- talerøret for producenter og forhandlere af medicinsk udstyr i Danmark
- udbyder af branchespecifikke kurser af høj kvalitet
- centralt placeret i internationale harmoniseringsbestræbelser
- en netværksorganisation, hvor forholdet mellem kontingent og udbytte opfattes positivt

Værdigrundlag

Medicoindustrien arbejder på et højt etisk og fagligt niveau for en positiv og balanceret varetagelse af patienters, professionelles, samfundets og branchens interesser.

In order to cover the need for **exchange of experience**, Medicoindustrien must:

- organise meetings and committee work

In order to cover the need for **up-to-date training**, Medicoindustrien must be able to:

- define, develop, market and hold courses specific to the industry.

Positioning Basis

Medicoindustrien wishes to be recognised in its business environment and society in general as:

- a sound and reliable business partner/sparring partner using a professional approach
- the spokesbody of manufacturers of and dealers in medical devices in Denmark
- a provider of high-quality courses specific to the industry
- a key player in the harmonisation of international rules
- a network organisation perceived to provide value for the annual membership fees

Basic Values

Medicoindustrien's activities are based on high ethical and professional standards. Medicoindustrien believes that the interests of patients, professional caregivers, society and the industry can be cared for in a positive and balanced spirit.

Medlemmer

Members

Accoat Medical	Agfa-Gevaert A/S	Alcon Danmark A/S	Ambu A/S	Astra Tech A/S
Bang & Olufsen Medicom a/s	Baxter A/S	Becton Dickinson a/s	Biofarma Logistik A/S	Biomet Danmark ApS
Karen Blok Specialiteter	Boston Scientific Nordic AB	B. Braun Medical A/S	Carmo A/S	Cartificial A/S
Chempaq A/S	Chempilots a/s	CMD Consulting A/S	Coloplast A/S	Contura International A/S
ConvaTec	William Cook Europe ApS	Danpleje A/S	Dansk Medico Service	Ferrosan A/S
Force Technology	Grøndorf Medical A/S	Guidant Denmark A/S	Paul Hartmann A/S	Hemax Medical ApS

InterV / PBN Medicals Denmark A/S	A. Johnsen Industri A/S	Johnson & Johnson	Kaiserplast A/S	Kebo Med A/S
Kendan A/S	Kirudan A/S	Kivex A/S	Knudsen Plast A/S	Kodak A/S
H. Dam Kærgaard A/S	LJ Medical ApS	Lohmann & Raucher A/S	3M A/S	Meda AS
Medical Equipment ApS	Mediplast A/S	Medtronic-ViCare A/S	Millimed A/S	Mærsk Andersen as
Mölnlycke Health Care A/S	N. C. Nielsen Hospitalsudstyr A/S	NorDiaTech A/S	Nordic Medical Supply A/S	Novo Nordisk A/S
Novozymes Biopolymers A/S	Olympus Danmark A/S	Oriola A/S	Osmedic	Pall Norden - Filial af Pall Norden AB

Philips
Medico A/S

PreciSense A/S

Pro-meduc A/S

Protese-
kompagniet A/S

Regent Medical

Rüsch
Danmark ApS

Santax
Medico A/S

Scan Care ApS

Sectra A/S

Seelen læge- og
hospitalsartikler ApS

Siemens
Medical Solutions

Simonsen &
Weel A/S

Smith &
Nephew A/S

Sterigenics
Denmark A/S

Sterisol
Danmark A/S

Karl Storz - Endo-
skopi Danmark A/S

Inge-Lise
Sørensen ApS

Stryker Danmark

Synthes A/S

Tamro
MedLab
A/S

Teknologisk Institut
Danish Technological Institute

Terumo Denmark
Filial af Terumo
Sweden AB

TGm Teknik A/S

K. V. Tjellesen A/S

Torsana A/S

TriVirix
Denmark ApS

Tyco Healthcare
Danmark

Unomedical a/s

ViCare
Medical A/S

Vingmed
Danmark A/S

Bestyrelsen | *Board of Directors*

1 2 3 4 5 6 7 8

Formand
Chairman
MOGENS PEDERSEN (6)
Corporate Affairs Officer

Coloplast A/S

Næstformand
Vice-Chairman
JØRGEN THANNING (7)
Direktør
General Manager

Siemens Medical Solutions

Kasserer
Treasurer
PETER MAGLEHØJ HANSEN (1)
Logistikchef
Logistic and Customer Service Manager

William Cook Europe ApS

JON BINGEN-JACOBSEN (8)
Adm. direktør
Managing Director

Synthes A/S

SØREN GRØNDORF (2)
Adm. direktør
Managing Director

Grøndorf Medical A/S

STEEN JUEL NIELSEN (3)
Adm. direktør
Managing Director

Torsana A/S

KIM STEENGAARD (5)
Direktør
Vice President

Novo Nordisk A/S

MICHAEL THORBEK (4)
Adm. direktør
Managing Director

Astra Tech A/S

Sekretariat | *Secretariat*

DITTE NØRGAARD-ANDERSEN

Cand. jur. Ditte Nørgaard-Andersen er direktør og daglig leder af sekretariatet. Samtidig er hun foreningens repræsentant i mange af de nationale såvel som internationale råd og udvalg, hvor foreningen er repræsenteret.

DITTE NØRGAARD-ANDERSEN

Ditte Nørgaard-Andersen, Master of Laws, is Director General of Medicoindustrien and manages the day-to-day activities of the secretariat. She also represents Medicoindustrien on many national as well as international councils and committees.

ANNE ANDERSEN

Anne Andersen er engelsk korrespondent. Hun er den daglige kontaktperson for medlemmerne og er samtidig ansvarlig for Medicoindustriens administration og regnskabsføring.

ANNE ANDERSEN

Bi-lingual secretary Anne Andersen is in charge of the basic, daily contact with member companies. Her second language is English. Anne is responsible for Medicoindustrien's administration and keeping of accounts.

LENE LAURSEN

Cand. jur., LI.M. Lene Laursen varetager rådgivning inden for udbuds- og konkurrenceretlige spørgsmål. Lene yder desuden sekretariatsbistand for de tre udvalg vedrørende det danske marked samt lovgivningsudvalget, og er Medicoindustrien's repræsentant i EUCOMED's lovgivningsgruppe.

LENE LAURSEN

Lene Laursen, Master of Laws, is responsible for advice to the members in the area of public procurement and competition law. In addition, Lene provides assistance to the three Committees on Danish Market Conditions and the Committee on Legal and Regulatory Affairs. Lene is Medicoindustrien's representative in the EUCOMED Regulatory Focus Group.

MOGENS QVIST FRANDSEN

Mogens Qvist Frandsen er uddannelseskonsulent med ansvaret for Medicoindustriens uddannelses- og kursusaktiviteter herunder Medicokonsulentuddannelsen. Mogens er Cand. merc. i strategi & ledelse.

MOGENS QVIST FRANDSEN

Mogens Qvist Frandsen is responsible for course activities in Medicoindustrien. This also includes the education programme for medical devices sales and marketing people. Mogens is Master of Science in Economics and Business Administration (strategy and management).

JETTE LØFQVIST

Jette Løfqvist er sekretær og ansvarlig for gennemførelsen af Medicoindustrien's kursusaktiviteter.

JETTE LØFQVIST

Jette Løfqvist, secretary, is responsible for the practical organisation of the association's course activities.

JESPER RÜDIGER

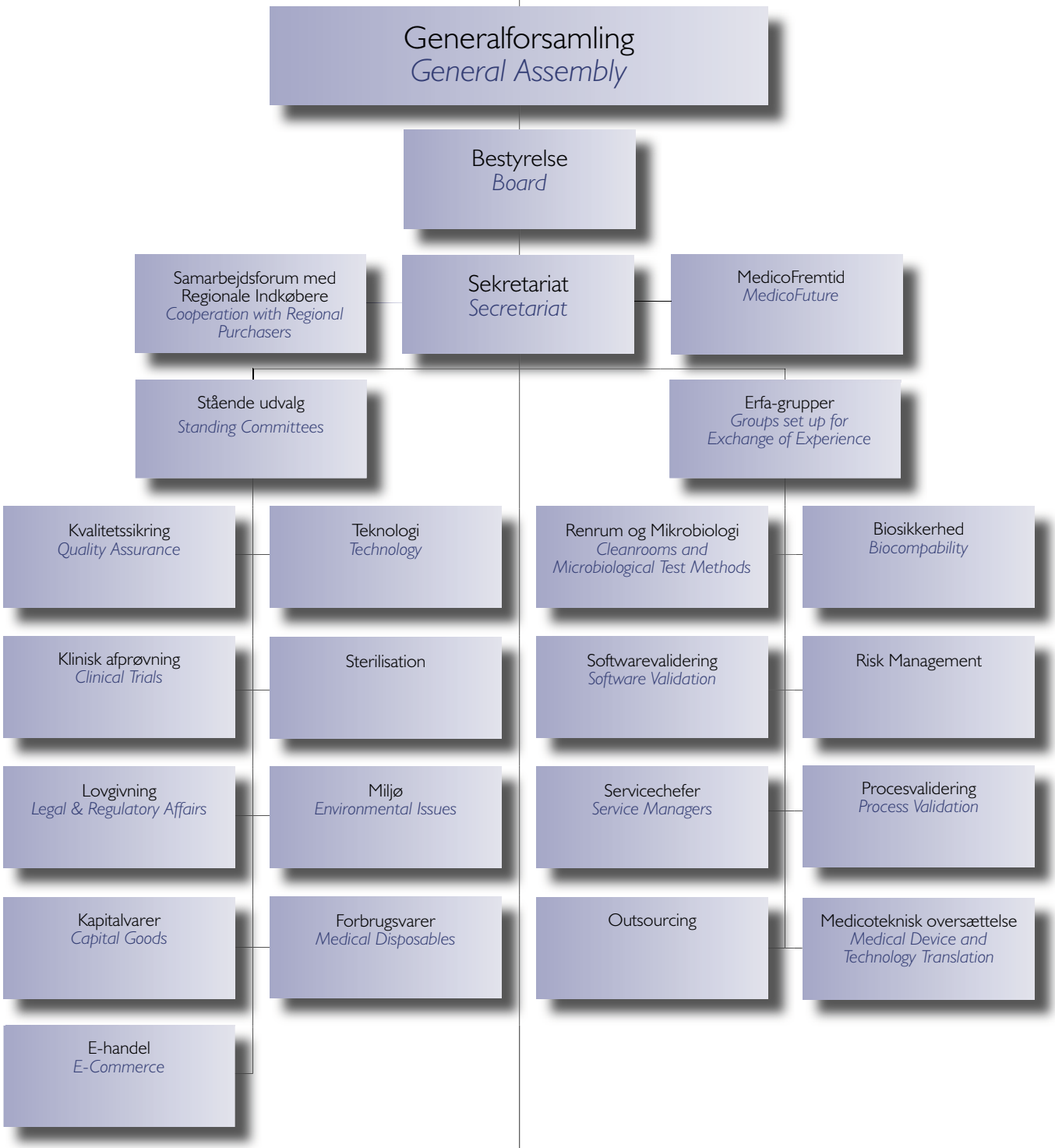
Jesper Rudiger studerer International Business ved Handelshøjskolen. Jesper er sekretariatets studentermedhjælper og ansvarlig for indsamling og bearbejdning af data om medicoindustrien til brug for organisationens branchestatistikker.

JESPER RÜDIGER

Jesper Rüdiger is a student of International Business at Copenhagen Business School and the secretariat's student assistant. He is responsible for collecting and processing data about the medical device industry for Medicoindustrien's industry statistics.

Medicoindustriens organisationsplan

Medicoindustrien's Organisation Chart



Den globale udfordring

Samarbejde bliver nøgleordet, hvis vi også fremover skal have en betydelig medicoindustri i Danmark. Den kinesiske drage er vågnet og udfordrer os. Når man kan få medarbejdere, der er villige til at arbejde for 6 kr. i timen, så skal vi andre til at lave noget andet end at samle komponenter.

Vi skal ikke gå i panik, men vi skal tænke os godt om og tænke nyt. Danmarks fremtidige jobs ligger blandt andet i sundhedsindustrien. Vi skal udnytte vores evne til at samarbejde på tværs af grupper, etablere partnerskaber, sætte brugeren i centrum og skabe helhedsløsninger. Disse kompetencer giver os nogle gode forudsætninger for at realisere potentialet i vores industri.

Innovationscenter for medicoindustrien

Danmark har med baggrund i et historisk, offentligt og skattebetalt sundhedssystem fostret en række unikke medicoprodukter og serviceydelser, som efterfølgende har kunnet danne baggrund for en betydelig international afsætning. Der er derfor god grund til at optimere en sådan udvikling, som både øger livskvaliteten og fremmer forretningsskabelsen til gavn for individer og samfund.

Nye ideer og koncepter opstår typisk ved interaktion imellem behandlere, forskere og brugere indenfor sundhedsvæsenet.

Deraf følger, at idéskaberne generelt vil være uden den fornødne kommercielle og forretningsmæssige forståelse, ligesom kendskabet til produktudvikling og de særlige kliniske og dokumentationsmæssige krav, der stilles i medicoindustrien, ikke er paratviden.

Modsat har de etablerede virksomheder vanskeligt ved at satse uden for deres kerneområder, uden at der eksisterer et veldokumenteret beslutningsgrundlag.

Der er derfor, for både leverandører, aftagere og samfundet i almindelighed, sund fornuft i at yde en særlig indsats for at identificere og modne nye produkter og services frem til kommerciel udnyttelse.

The global challenge

Collaboration is the watchword if we are to maintain a vital medical device industry in Denmark in future. The Chinese dragon has raised its head and is challenging us. When it is possible to recruit a workforce willing to work for a small fraction of our rates, the rest of us must do other jobs than assembling components.

We should not panic, but think carefully and think ahead. Many of Denmark's future jobs will be in the healthcare industry and the way forward is utilising our skills to collaborate across groups, forge partnerships, develop holistic solutions and put users first, ensuring a solid platform for realising the potential of our industry.

Innovation centre for the medical device industry

Against the background of our historic, public and tax-funded health system, Denmark has developed a range of unique medical device products and services, which have also enabled us to generate substantial sales to markets abroad. Thus, there is every reason to optimise this development, which offers a higher quality of life while also creating business opportunities that benefit individuals and society in general.

New ideas and solutions are typically fostered through interactions between care providers, researchers and users in the healthcare service.

However, those who conceive ideas will frequently be without the necessary commercial and business expertise or insight into product development. In addition, they are not familiar with the specific clinical and documentation requirements imposed on the medical device industry.

In contrast, established companies have difficulties moving beyond their core business without having a well-documented basis on which to make decisions.

Making a special effort to identify new products and services and move them into the industry's pipeline will therefore make good sense to suppliers, purchasers and society as a whole.

Medicoindustrien er en oplagt operatør af en sådan ydelse på grund af sin medlemskreds, kontakt til det offentlige, særlige viden om branchens specielle dokumentationskrav og relativt virksomhedsneutrale stilling i forhold til kunder og leverandører.

Det er baggrunden for, at Medicoindustrien ønsker at etablere en fødselshjælperfunktion under titlen *MedicoInnovation*.

Der er allerede fra mange forskellige sider rådgivnings- og støtteinitiativer til innovation og virksomhedsetablering. Det er ikke målet at dublere allerede eksisterende ydelser, men derimod at yde en målrettet hjælp til projektets målgruppe, som dels vejleder dem indenfor de eksisterende ydelser, og dels supplerer med de særlige aspekter, som er gældende for medicoindustrien.

MedicoInnovation skal således være et faciliterende omdrejningspunkt for samspillet mellem medicoindustrien, hospitaler, vidensmiljøer og afledte virksomheder og aktiviteter fra disse miljøer.

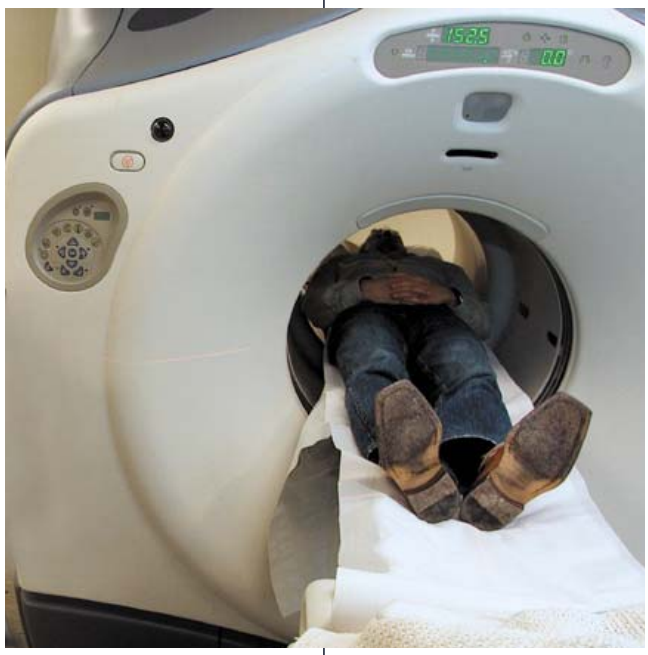
Medicoindustrien is an obvious steward for an initiative of this character thanks to our membership, contacts with the public sector, long familiarity with the industry's special documentation requirements and our relatively neutral position in relation to customers and suppliers.

This is the reasoning behind Medicoindustrien's aspirations to promote the facilitating initiative entitled *MedicoInnovation*.

A variety of actors have already launched programmes that provide counselling and support to innovation and new business ventures. Our goal is not to duplicate their efforts but to offer focused help to the target group of the planned project and provide counselling in the context of existing services and adding on the specific aspects distinct to the medical device industry.

Thus, MedicoInnovation is meant to serve as a facilitating hub for interaction between the medical device industry, hospitals, knowledge environments and derivative companies as well as activities from these environments.

MedicoInnovation forventes etableret i 2005. Der har allerede været en del presseomtale af tankerne om et sådant center, som har resulteret i mange positive tilkendegivelser fra såvel sundhedspersonale som finansielle investorer.



Undersøgelse af innovation i medicoindustrien

For at opnå større indsigt i, hvad der driver innovation, og hvilke rammebetingelser virksomhedernes innovation baserer sig på, indgik Medicoindustrien i 2004 et samarbejde med Økonomi- og Erhvervsministeriets enhed for erhvervs- og økonomisk forskning og analyse (FORA) om en analyse af medicoindustrien.

Innovationsrådet

I 2004 blev Medicoindustrien medlem af Innovationsrådet, som er et bredt og internationalt sammensat netværk af nytænkere, der skal identificere Danmarks muligheder i det globale videnssamfund. Innovationsrådet vil blandt andet give konkrete bud på, hvordan Danmark kan udvikle nye vidensmiljøer og industrier der kan sikre, at fremtidens arbejdspladser også flytter til Danmark.

Innovationsrådet er stiftet af Økonomi- og Erhvervsministeriet, Ministeriet for Videnskab, Teknologi og Udvikling, Undervisningsministeriet, Danfoss, FUHU, Novozymes og Finansrådet på initiativ af Huset Mandag Morgen.

MedicoFremtid

Samspil er vigtigt. Derfor oprettede Medicoindustrien for et år siden MedicoFremtid, som repræsenterer de fagligt stærkeste kræfter i Danmark indenfor medicoteknologi. MedicoFremtid består af deltagere fra forskningsverdenen med specielt fokus på medicoområdet, sygehusverdenen, samt medicovirksomheder i Danmark. Medicoindustrien varetager sekretariatsbetjeningen.

Formålet med netværket er at fremme udviklingen i den danske medicoindustri gennem et udvidet samarbejde mellem medicoindustrien og teknisk og sundhedsvidenskabelig forskning, udvikling og uddannelse.

The goal is to set up MedicoInnovation in 2005 and the plans have already received a good deal of press coverage, which has evoked considerable positive response from both healthcare professionals and financial investors.

Analysis of innovation in the medical device industry

In 2004, Medicoindustrien joined forces with FORA, the centre for economic and business research and analysis of the Ministry of Economic and Business Affairs, to collaborate on a study of the medical device industry in order to gain greater insight into the drivers of innovation and the framework conditions that underpin corporate innovation.

Innovation Council

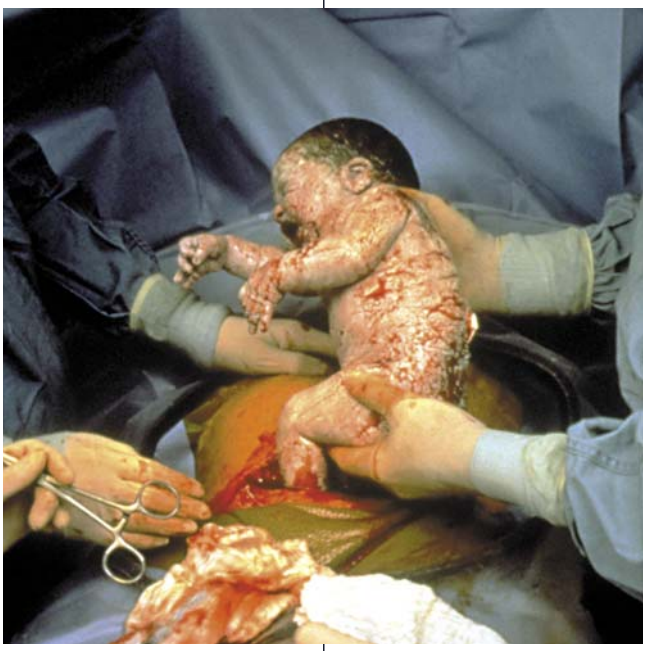
In 2004, Medicoindustrien became a member of the Innovation Council, a broad network of innovators with an international composition created to identify Denmark's potential in the global knowledge society. For example, the Innovation Council will provide concrete input to how Denmark can develop new knowledge environments and industry sectors with the capacity to ensure that the jobs of the future will be placed in Denmark too.
The Innovation Council was set up by the Ministry of Economic and Business Affairs, the Ministry of Science, Technology and Innovation, the Ministry of Education, Danfoss, the Society for the Advancement of Business Education, Novozymes and the Danish Bankers' Association upon an initiative from the news think tank 'Huset Mandag Morgen'.

MedicoFuture

Interaction is crucial. One year ago, Medicoindustrien therefore launched MedicoFuture, gathering the strongest medical technology professionals in Denmark. MedicoFuture includes partners from the research world specialising in medical technology, the hospital sector and medical device manufacturers. Medicoindustrien provides secretariat services to this professional network.

Et af de første projekter, der er taget fat på, er at få tegnet et kort over, hvem der er specialister i hvad. Det må ikke bero på en tilfældighed, om man finder den rette forsker eller virksomhed, der kan arbejde videre med nye idéer.

MedicoFremtid vil blive en vigtig partner for Medico-Innovation.



Uddannelse

Medicoindustriens evne til at udvikle produkter, der afspejler brugernes behov, vil være afgørende for vores fremtid. Det er derfor brugernes behov, der skal være centrum og fokus for udviklingen. Det behov ser kineserne ikke bedre end vi og heller ikke før os. Så nøgleordet er udvikling! Udvikling af tanker, ideer, projekter, behov, kombinationer og løsninger. Det kræver viden, og det, som vi også er gode til, nemlig samarbejde. Vi skal tænke nyt hele tiden, ellers bliver vi overhalet af andre, der står med samme udfordring som vi med produktion, der flytter. Det er en spændende men vanskelig udfordring.

Det vil kræve veluddannede og kvikke hoveder at kunne definere og omsætte patienternes behov til nye produkter og udnytte de seneste teknologier. Der er derfor behov for at øge investeringerne i de naturvidenskabelige uddannelser, der kan sikre de nødvendige vidensressourcer i Danmark. Vi glæder os over de branchespecifikke uddannelser, som det er lykkedes at få oprettet. Uddannelser hvor ingeniørfaget kombineres med sundhedsfaglige fag. Det viser sig, at mange unge synes, at uddannelserne er interessante, fordi de kombinerer det naturfaglige med det humanistiske, og det er netop det, vi i medicobranchen skal leve af og overleve på fremover.

The objective for the network is to boost development in the Danish medical technology industry through expanded collaboration between the industry and technical and health science research, development and education.

Among the first projects is drawing a map of who is specialising in what, since finding the right researcher or company to head the further development of new ideas should not be left to chance.

MedicoFuture will also become an important partner to MedicoInnovation.

Education

The future of the medical device industry will depend on our ability to design products that match the users' needs. All development should therefore focus on them. In China, they do not see those needs better than we do and not sooner than we do. The key is development! Development of thoughts, ideas, projects, needs, combinations and solutions. It requires knowledge and another of our prime skills: collaboration. We have to think innovatively at all times, for if we do not, we will be overtaken by other players who are facing the same prospect of manufacturing activities being moved abroad. The challenge is interesting but difficult.

It will require well-educated and skilful people who can define patients' needs and translate them into new products, harnessing the latest technology. Thus, it is vital to boost investment in the natural science degree programmes that can ensure the necessary knowledge resources in Denmark. We have therefore welcomed the industry-oriented degrees that have been introduced recently, combining engineering and medical disciplines. The programmes appeal to many students because they combine the natural science field with the humanistic perspective, which is essentially what the medical device industry depends on for its future earnings and survival.

Genbrug af medicinske éngangsartikler

Managing Director
Peter Schröer
Ethicon Endo-Surgery

Vice president
Fredric Willem Lindemans
Medtronic Research Center

Medicoindustrien rejste i 2004 en debat om genbrug af éngangsartikler. Det gjorde vi, fordi der hver dag genbruges medicinske éngangsartikler på de danske sygehuse, og fordi ingen gør noget ved det. Vi havde imidlertid hellere set, at andre havde taget fat om problemet, fordi industriens motiver uvægerligt bliver mistænkeliggjort – »de er bare ude på at sælge flere produkter og dermed tjene flere penge«.

Selvfølgelig er industrien interesseret i at sælge mere, men det er nu det faktum, at der er et kæmpe misforhold mellem sikkerheden og kontrollen i virksomhederne, og den efterfølgende håndtering af éngangsartiklerne på sygehusene, der ryster branchen. Derfor arrangerede vi en høring om genbrug den 20. februar 2004.

Sygehusene eksperimenterer efter vores opfattelse med patienterne, når de genbruger udstyr, som kun er designet, fremstillet og godkendt til at blive anvendt én gang. Vi undrer os over, at der gælder ét sæt sikkerhedsregler for det udstyr, der produceres og sælges fra producenterne og et andet eller rettere slet ingen regler for det, der foregår på sygehusene, eller for dem, de vælger at udlicitere »rengøringen« til. Hvorfor skal sikkerheden kun omfatte de patienter, udstyret bliver anvendt på første gang?

Statens Serum Institut har ved flere lejligheder sagt, at det genbrug, der finder sted på de danske sygehuse er uacceptabelt, og de har oven i købet kaldt det for en subkultur, der bør ophøre. Alligevel har tilsynsmyndighederne ikke grebet ind. De har i stedet sat kikkerten for det blinde øje og lader som ingenting.

Branchen kan godt forstå, at sygehuse i økonomisk trængte tider har svært ved at smide dyrt indkøbt udstyr ud efter kun at have brugt det én gang. Men vi har ingen forståelse for, at man vælger en løsning, hvor man genbruger udstyr, der ikke er designet til det. Hvis produkter skal kunne genbruges, skal man allerede i designfasen medtænke rengøringen og genanvendelsesmulighederne. Det sker selvfølgelig ikke nu, da det ikke er meningen, at produkterne skal genbruges.

Reuse of single-use medical devices

Lægelig direktør/Medical Director
Torben Mogensen
Hvidovre Hospital

Kresten Philipsen, tidligere formand for Dansk Selskab for Patientsikkerhed
Former Chairman of the Danish Patient Safety Foundation

Medicoindustrien raised debate about the reuse of single-use devices in 2004. We did so because single-use devices are reused every day at Danish hospitals, and no one does anything about it. We had, however, rather seen someone else address the issue, because the industry's motives will invariably be regarded with suspicion – "All they want is to sell more products and make more money".

Naturally, the industry is interested in selling more products, but the sharp contrast between the safety and control standards of companies and the subsequent handling of single-use devices by hospitals is the reality that has shaken the industry. Therefore, we organised a hearing on the reuse issue on 20 February 2004.

Hospitals experiment with patients, in our opinion, when they reuse devices that were designed, manufactured and approved to be used only once. We are astonished to see that one set of safety rules applies to devices manufactured and sold by

Tidligere overlæge/
Former Consultant Physician
Ole Bent Jepsen
Statens Serum Institut

Direktør/Director General
Ditte Nørgaard-Andersen
Medicoindustrien

Mogens Gyde
ordstyrer/Chairman

Margrethe Nielsen, sundhedspolitisk medarbejder i Forbrugerrådet
Health Policy Officer for the Consumer Council

Idéen om éngangsudstyr blev oprindeligt fostret af sygehusene for at undgå smitterisiko fra en patient til en anden, og fordi det var nemmere. Hvis forholdene nu har ændret sig, bør sygehusene indlede en dialog med producenterne om produktion af flergangsudstyr.

I Frankrig og England har sundhedsmyndighederne forbudt genbrug. I USA siger myndighederne, at eventuelt genbrug skal foregå under kontrollerede forhold. De stiller derfor krav om godkendelse af de produkter, der skal genbruges – ligesom man gør, første gang produkterne skal bruges.
Det er på tide, at de danske sundhedsmyndigheder kommer på banen i stedet for bare at se gennem fingre med, at der eksperimenteres med patienterne på de danske sygehuse. Og at patienter ikke fortsat holdes uvidende om, at de er med i eksperimenter med genbrug af engangsartikler.

producers, while another, or rather no rules at all, apply to the practice of the hospitals or the companies to which they choose to outsource the "reprocessing". Why should safety only be in operation for the patients treated with first-use devices?

The State Serum Institute has indicated on several occasions that the reuse practice of Danish hospitals is unacceptable, and even referred to it as a subculture that should be eradicated. Nevertheless, the supervisory authorities have done nothing to intervene. They have turned a blind eye to the problem, ignoring that it exists.

The industry fully understands that in times of financial restraint hospitals are reluctant to discard expensive devices having used them only once. We do in no way understand, however, that they opt for the solution of reusing devices that were not designed for it. If products have to be reusable, the reprocessing and reuse applications must be thought into the devices already at the design stage. Naturally, this is not done now, because the products are not intended for reuse.

The concept of single-use devices was originally promoted by hospitals in order to avoid the risk of contamination from one patient to the other and because single use was easier. If the situation has now changed, the hospitals should initiate dialogue with the manufacturers for development of multiple-use devices.

In France and Great Britain, the health authorities have banned reuse. In the USA, the authorities insist that any reuse must be practised under controlled conditions and have, accordingly, set requirements for approval of products to be reused – like they have done for products to be used for the first time.
It is high time that the Danish health authorities address the issue, instead of being blind to the fact that patients are exposed to experiments at Danish hospitals. And patients should no longer be kept in ignorance of the truth that they take part the experiment of reusing single-use medical devices.

Gennembrud for elektronisk handel med amterne

Amtsrådsforeningen gik foran i den offentlige sektor, da den i 2003 indgik en samarbejdsaftale med Medicoindustrien om det såkaldte Medicoprojekt. Det er det fælles e-handelsprojekt, der skal gøre samhandel mellem sygehusene og deres leverandører af medicinsk udstyr mere effektiv.

Kontorchef Niels Mortensen
Amtsrådsforeningen
Head of Department, Danish Regions

Projektet sluttede ved årsskiftet 2004/2005, hvor der var enighed om standarder og principper for elektronisk handel mellem parterne.
Der er nu skabt enighed om rammerne for et fælles elektronisk varekatalog og om, hvordan der skal kommunikeres i forbindelse med afgivelse af ordrer, fakturaer og betalinger. Ikke alle virksomheder har nået at lægge deres produkter ind i kataloget endnu, men takket være et forbilledligt eksempel på offentligt-privat samarbejde er parterne nu i stand til at køre fuldt integreret elektronisk handel i et hidtil uset omfang.

Alle 14 amtskommuner og 39 af Medicoindustriens medlemsvirksomheder deltog i projektet. To amter har sammen med fem virksomheder fungeret som piloter. De har testet ideerne af, inden de andre gik i gang. Projektet har kostet mange ressourcer, men fremover vil der til gengæld kunne spares betydelige ressourcer i både amter og i virksomheder. Det er afgørende for virksomhederne, at kommunerne også kommer med, så al handel kører på det samme system.

Medicoprojektet blev i slutfasen forstyrret, da også Finansministeriet erkendte, at der kan hentes effektiviseringsgevinster hjem ved at handle elektronisk. Ifølge en konsulentrapport kan der spares ca. 1,1 mia. kr., hvis det offentlige begynder at handle elektronisk. Med denne besparelse for øje besluttede Finansministeriet i slutningen af 2004, at alle fakturaer til det offentlige, og det er mere end 18 millioner om året, skal håndteres elektronisk fra den 1. februar 2005.

Det er forståeligt, at også Finansministeriet er interesseret i hurtige gevinster, men ved her og nu at indføre elektroniske fakturaer efter en dansk standard opstod der komplikationer i forhold til Medicoprojektet, som kører efter en international standard. Den danske standard har primært fokus på den elektroniske regning. Medicoprojektet har imidlertid et bredere fokus og er på forkant med udviklingen, idet vi forsøger at høste gevinsten ved et integreret indkøbsforløb med både ordreafgivelse, fakturering og betaling.

Breakthrough for electronic commerce with regions

Bent Hansen, formand for Amtsrådsforeningens sundhedsudvalg
Chairman of the Healthcare Group, Danish Regions

Danish Regions spearheaded the public sector when, in 2003, they entered into an agreement with Medicoindustrien for cooperation on the so-called Medical Device Project, the joint e-commerce project aimed to boost the efficiency of the trading relations between hospitals and their suppliers of medical devices.

The project was completed at the turn of the year 2004/2005, when the parties had agreed on the standards and principles for e-commerce between them. They had also reached agreement on the structure of the shared electronic product catalogue and how to communicate to place orders, issue invoices and pay for products. Not all companies has yet had time to integrate their products in the catalogue, but thanks to exemplary public/private sector collaboration the two sides are now able to engage in fully integrated electronic commerce to an unprecedented extent.

Direktør/Director General
Ditte Nørgaard-Andersen,
Medicoindustrien

Indkøbschef
Chief Buyer, Region of Copenhagen
Oluf Ravn, Københavns Amt

Salgs- og marketingdirektør
Sales- and Marketing Director
Niels Røddik, 3M A/S

Finansministeriets intervention forsinkede Medicoprojektet, fordi amterne pludselig fik travlt med at opfylde de nye krav til håndtering af fakturaer efter den danske standard. Medicoindustrien var fast besluttet på, at de nye krav fra Finansministeriet ikke måtte bremse eller genere Medicoprojektet. Vi kontaktede derfor Videnskabsministeriets IT- og Telestyrelse og efterlyste et konverteringsværktøj fra den ene standard til den anden. Det har vi nu fået, og Medicoindustriens virksomheder kan derfor arbejde videre efter den internationale standard og konvertere til den danske standard, når kunder måtte ønske den type fakturaer.

2005 ser derfor ud til at blive året, hvor sygehusene og deres leverandører af medicinsk udstyr vil handle fuldt integreret. Hvis også kommunerne tilslutter sig modellen, kan alle parter opnå sin del af den store besparelse, der ligger i elektronisk samhandel.

All 14 regions and 39 of Medicoindustrien's member companies joined the project. Two regions and five companies acted as pilots, testing all concepts before they were used by the rest of the participants. The project has required many resources but will allow both regional authorities and companies to cut their costs substantially in future. To the company partners, it is vital to have the local authorities linked up too, allowing all product trading to run on the same system.

The Medical Device Project was slowed down at the final stage when also the Finance Ministry realised the scope for efficiency benefits from electronic business. A consultants' report has estimated that the potential savings to be gained by the public sector from conversion to electronic commerce will be approx. DKK 1.1 billion. Spurred by this kind of savings potential, the Finance Ministry decided in late 2004 that all invoices to the public sector, in fact more than 18 million a year, had to be handled electronically as of 1 February 2005.

That also the Finance Ministry is interested in quick gains is understandable. However, by acting on the spur of the moment, introducing electronic invoicing based on a Danish standard, the Ministry caused problems in relation to the Medical Device Project, which is based on an international standard. The Danish standard has its key focus on the electronic invoice. The Medical Device Project, in contrast, is at the cutting edge of developments with a broader focus, aimed to reap the benefits of an integrated purchasing process that includes order placing, invoicing and payment.

The Finance Ministry's intervention stalled the Medical Device Project because the regions were suddenly busy meeting the new requirement to handle invoices based on the Danish standard. Determined that the new requirements from the Finance Ministry should not be allowed to halt or impair the Medical Device Project, Medicoindustrien contacted the IT and Telecom Agency under the Science Ministry asking for a tool for conversion from one standard to the other. We have received it now, and Medicoindustrien's members can continue using the international standard and convert to the Danish one whenever customers may request invoices in that format.

Thus, 2005 promises to be the year in which business between hospitals and their suppliers of medical devices will run in a fully integrated process. If the system is adopted by local authorities as well, all parties will receive their fair share of the significant savings potential of electronic commerce.

Medicokonsulent-uddannelsen

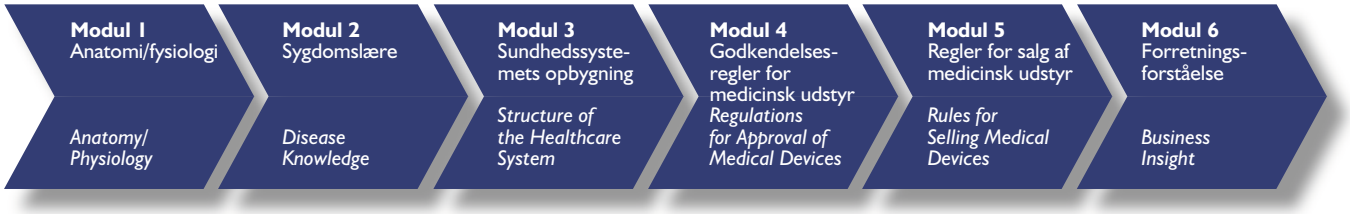
I 2004 lancerede Medicoindustrien sin nye konsulentuddannelse. Der er tale om en uddannelse for salgs- og marketingmedarbejdere i medicoindustrien. Uddannelsen skal sikre, at medarbejderne har en basisviden, der sætter dem i stand til at arbejde professionelt og effektivt med salg af medicinsk udstyr.

Uddannelsen er bygget op om følgende moduler:

Medical Device Sales Consultant Programme

In 2004, Medicoindustrien launched our new consultant training programme for sales and marketing people in the medical device industry. It is aimed to provide them with the basic knowledge necessary to handle sales of medical devices efficiently and professionally.

The programme comprises the following six modules:



Hvert modul afsluttes med en skriftlig eksamen.

15 salgs- og marketingfolk fra branchen startede i januar 2004 på det pilothold, der skal teste uddannelsen. Deltagerne har vidt forskellig baggrund; der er således både sygeplejersker, en radiograf, en HD i udenrigshandel, en cand. merc., en ingeniør, en apoteksassistent og en maskinmester. Holdet nåede at gennemføre fire af de seks moduler i 2004, resten gennemfører de i første halvår af 2005. Der har været stor entusiasme på holdet, selvom ikke alle har bestået alle eksamener. Der skal ydes en stor indsats med forberedelse til såvel undervisning som eksamen.

For at sikre respekten for uddannelsen benyttes kun eksterne undervisere. Lærerne kommer fra advokatvirksomheder, myndigheder, konsulentvirksomheder og sundhedssystemet. Underviserne både udfærdiger og retter eksamensopgaverne.

De første medicokonsulenter får deres eksamensbeviser i juni 2005. Titlen 'Medicokonsulent' er blevet varemærkeregistreret, så fremover vil det kun være dem, der har bestået alle modulerne på uddannelsen, der kan kalde sig 'Medicokonsulent'.

Sundhedssystemet har modtaget initiativet meget positivt. Professor Dr. med. Peter K. Paulsen fra Skejby Sygehus siger: »Vi handler med dygtige firmaer, men skal jeg være helt ærlig, kan det undertiden hos de yngste sælgere knibe med basisviden om det, de sælger og det, vi bruger udstyret til.« Derfor hilses Medicoindustriens nye uddannelse velkommen.

Each module is completed with a written exam.

In January 2004, a group of 15 people holding sales and marketing jobs in the industry joined the pilot class that would test the programme. Spanning a variety of backgrounds the group includes nurses, radiographers, people with a diploma in export marketing and degrees in business economics and engineering, a pharmacy assistant and a single chief engineer. The class succeeded in completing four of the six modules in 2004 and will take the last two in the first half of 2005. The class has been full of enthusiasm, even though everyone did not pass all exams. The programme requires a lot of hard work in preparing for both class sessions and exams.

To gain and maintain respect of the programme, external teaching resources are used exclusively. The teachers, recruited from law firms, regulatory authorities, consulting firms and the healthcare service, set and grade all exam papers.

The first medical device sales consultants will receive their diplomas in June 2005. The title of medical device sales consultant has been trademark registered to ensure that only persons who have completed all modules of the programme will be able to use the title of 'medical device sales consultant' in future.

The healthcare system has met the initiative with considerable appreciation. Professor Peter K. Paulsen, MD, from Skejby Hospital says: "We purchase products from skilful companies but, honestly, the youngest sales people may at times display a lack of basic knowledge about what they sell and what we use devices for." Medicoindustrien's new training programme is therefore very welcome.

MEDICO KONSULENT

Årets gang

Opinionspåvirkning, formidling, erfaringsudveksling, uddannelse og samspillet mellem den offentlige sektor og det private erhvervsliv. Det er fem punkter, der sammen og hver for sig er hjørnesten i Medicoindustriens idégrundlag. 2004 var rig på begivenheder og aktiviteter inden for disse områder. Mål blev nået og nye initiativer igangsat. Det er naturligt at beskrive dem under de samme hovedoverskrifter.

Opinionspåvirkning

Imageskabende

Medicoindustrien har i mange år kæmpet med det faktum, at ingen rigtig vidste, hvad ordet 'medico' eller 'medicinsk udstyr' dækkede over. Branchen er blevet blandet sammen med lægemiddelbranchen under begrebet medicinalindustrien.

Det har vi bevidst arbejdet på at ændre. I dag er mange journalister og politikere godt klar over, at medicoindustrien er en selvstændig industri, som er vidt forskellig fra lægemiddelindustrien, og at medicoudstyr er det tekniske udstyr, der blandt andet findes på sygehusene. Medicoindustrien bliver i dag ofte kontaktet af journalister, som skal vide noget om branchen, ligesom vi kontaktes af investorer. Den meget bevidste satsning på at gøre branchen kendt i medierne resulterede i megen fin presseomtale i 2004.

Highlights of the year

Shaping opinion, communicating information, sharing experience, supporting training and public-private sector interaction are five objectives which, combined and individually, constitute the cornerstone of Medicoindustrien's strategic business concept. 2004 was a year rich in events and activity in all five areas. Goals were attained and new initiatives launched. Thus, it is natural to report on them under the same main headings.

Shaping opinion

Image building

For many years Medicoindustrien had to deal with the fact that no one really knew the meaning of the term 'medical devices'. The industry was commonly confused with the pharmaceutical industry or believed to be part of it.

We have made consistent efforts to eradicate this confusion and today many journalists and politicians are fully aware that the medical device industry is a sector of its own, entirely separate from the pharmaceutical industry, and that medical devices comprise all the technical equipment used at hospitals, for example. Investors and journalists seeking information about our industry now frequently contact Medicoindustrien, and our determined commitment to earn media recognition of our industry was rewarded with fine press coverage in 2004.

Medicoindustrien ønsker at være den samlede branches talerør på såvel det sundhedspolitiske som det specifikke erhvervspolitiske område. Vi har i dag 90 medlemmer, som dækker stort set alt det udstyr, der bruges på sygehusene. Der kom 4 nye medlemmer til i 2004, og i første måned af 2005 kom yderligere 4 til.

Internationale relationer

Medicoindustrien er meget aktiv i den europæiske paraplyorganisation for medicinsk udstyr kaldet EUCOMED. Vi har en repræsentant i bestyrelsen og en i det fælles forum for de europæiske branchedirektører samt repræsentanter i de udvalg, som Medicoindustriens medlemmer finder relevante for de opgaver, der arbejdes med i organisationen.

Vi er også, som den eneste mindre organisation, repræsenteret i den virtuelle globale organisation kaldet 'Global Medical Technology Network' (GMTN). Her har vi et godt erfaringsudvekslingsforum, som udover Europa dækker Japan, USA, Australien og Canada.

Formidling af information

Medicoindustriens sekretariat fungerer i høj grad som formidlingscenter for medlemmerne. Organisationen er medlemmernes talerør overfor myndighederne, men herudover skabes der kontakt mellem sundhedspersonale og producenter, mellem udenlandske leverandører og danske distributører, mellem forskere og virksomheder, mellem universiteter og virksomheder. Så på mange måder er organisationen et omdrejningspunkt for branchen.

Nyhedsbreve

Megen af den information sekretariatet indsamler videreformidles til medlemmerne via det nyhedsbrev, der udgives to gange om måneden. Der blev udgivet i alt 20 nyhedsbreve i 2004.

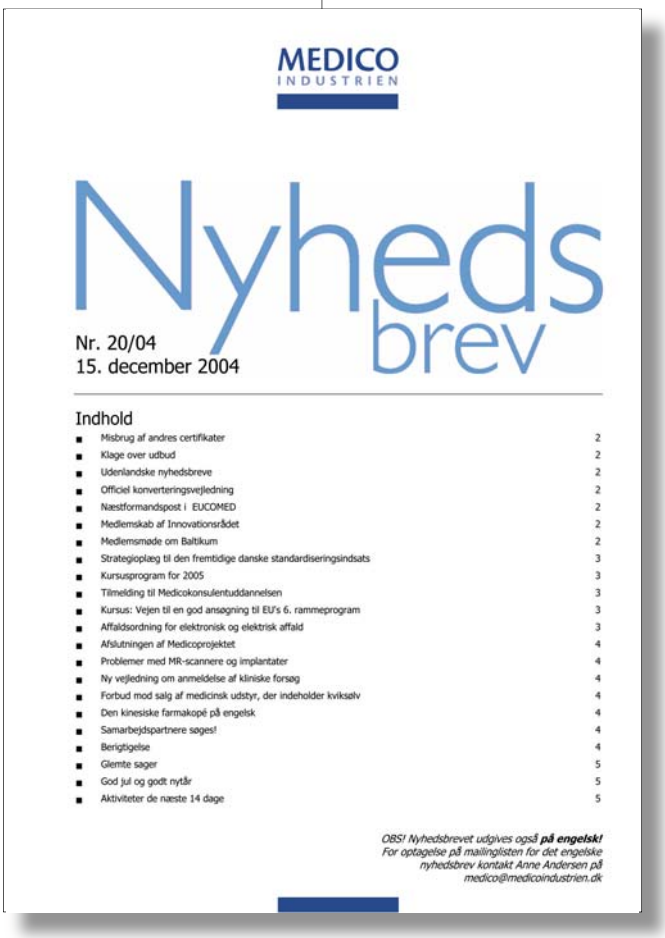
Medicoindustrien wants to be the voice of the entire industry in matters of both healthcare policy and specific areas of industrial policy. Today, we have 90 members, who supply essentially all equipment and devices used at hospitals. Four new members joined in 2004 and a further four were added in the first month of 2005.

International relations

Medicoindustrien is a highly active member of EUCOMED, the European umbrella organisation for medical devices. We have one representative on the board, one member of the council of European association secretaries and representatives on the committees relevant to the members of Medicoindustrien and the focus areas of our association.

We are also the only medium-sized association represented in the virtual, global organisation known as the Global Medical Technology Network (GMTN). Here we are part of a valuable forum, sharing experience across Europe, of course, as well as Japan, the USA, Australia and Canada.

Communicating information



MEDICO
INDUSTRIEN

Nyheds brev

Nr. 20/04
15. december 2004

Indhold

*OBS! Nyhedsbrevet udgives også **på engelsk!***
For optagelse på mailinglisten for det engelske nyhedsbrev kontakt Anne Andersen på medico@medicoindustrien.dk

Medicoindustrien's secretariat serves extensively as a communication centre for members. The association is the members' voice in relation to relevant authorities, and also ensures contact between healthcare professionals and manufacturers, foreign suppliers and Danish distributors and scientists and companies. Thus, in many ways, Medicoindustrien's role is the hub in the wheel of the industry.

Newsletters

Most of the information gathered by the secretariat is passed on to members via our bimonthly newsletter. Twenty newsletters in total were issued in 2004.

Hjemmeside

Hjemmesiden bliver i stigende omfang anvendt af såvel medlemmerne som omverdenen. Der var i 2004 gennemsnitlig 3.000 besøgende hver måned hvoraf 2.000 var unikke, dvs. forskellige brugere. Det er primært danskere der søger, men der er også en del fra andre EU-lande og fra USA - ja selv Kina er begyndt at vise sig i statistikkerne.

Rådgivning

Der ydes daglig megen telefonisk rådgivning til medlemmerne. Rådgivningen spænder bredt fra hjælp til fortolkning af godkendelsesreglerne, over elektronisk fakturering og sponsorering, til hjælp i forbindelse med udbudssager. Det sidste har ført til en del sager i Konkurrencestyrelsen, hvor Medicoindustrien har medvirket til, at flere udbud er blevet annulleret og omgjort.

Høring

Den 20. februar afholdt Medicoindustrien en meget velbesøgt høring om genbrug af medicinske engangsartikler. På høringen ridsede Ditte Nørgaard-Andersen fra Medicoindustrien situationen med genbrug op og fortalte om erfaringer fra udlandet. Herefter fortalte lægelig direktør Torben Mogensen fra Hvidovre sygehus, hvorfor han genbruger engangsudstyr, og overlæge Ole Bent Jepsen fra Statens Serum Institut fortalte om det pilotprojekt, han har stået i spidsen for om genbrug. Direktør Fredric Willem Lindemans fra Medtronic Research Center gennemgik kravene til godkendelse af medicinsk udstyr, og direktør Peter Schröer fra Ethicon Endo-Surgery fortalte om nogle europæiske studier af kvaliteten af engangsudstyr, der vaskes og resteriliseres. Endelig talte sundhedspolitisk ordfører Margrethe Nielsen fra Forbrugerrådet om patientens retsstilling i forbindelse med genbrug.

Website

Our website is used increasingly by members as well as users outside the industry. In 2004, the average number of visitors was 3,000 a month, 2,000 of them unique, meaning they were different users. Visitors are primarily Danish but we have also recorded several from other EU states and the USA – and even China is beginning to show in our statistics.

Advisory services

The secretariat staff provides telephone advice to members every day on a host of topics ranging from interpretation of certification rules, electronic invoicing and sponsoring to assistance in dealing with specific tender procedures. Procurement issues prompted our submission of several cases to the Competition Authority and, ultimately, Medicoindustrien contributed to the cancellation or relaunch of several tender procedures.

Hearing

On 20 February 2004, Medicoindustrien hosted a well-attended hearing about the reuse of disposable medical devices. Ditte Nørgaard-Andersen, Director General of Medicoindustrien, outlined the reuse issue and described experience from abroad. Torben Mogensen, Medical Director of Hvidovre Hospital, talked on why he reuses single-use devices and Ole Bent Jepsen, Chief Physician, the State Serum Institute, presented the reuse pilot project, which he had headed. Director Fredric Willem Lindemans from Medtronic Research Center reviewed the requirements for approval of medical devices, while Director Peter Schröer from Ethicon Endo-Surgery presented a number of European studies of the quality of single-use devices that have been processed and resterilised. Finally, Margrethe Nielsen, Chief Health Policy Officer of the Consumer Council, talked about the legal rights of patients in relation to the reuse of devices.

Seminar

Den 14.-15. april var der fællesseminar for 'Regionale Indkøbere' (sygehusindkøbernes forening) og Medicoindustrien på Koldingfjord med knapt 100 deltagere. Overlæge Beth Lilja Pedersen fra 'Dansk Selskab for Patientsikkerhed' talte om patientsikkerhed i relation til indkøb af medicinsk udstyr. Derudover talte kommunalforsker ved Syddansk Universitetscenter Roger Buch om strukturkommissionens rapport og konsekvenserne heraf. Der var desuden afrapportering fra de fælles arbejdsgrupper om blandt andet brugen af udbudsstandarderne og det fælles e-handelsprojekt, som er beskrevet andetsteds i beretningen.

Overlæge Beth Lilja Pedersen, Dansk Selskab for Patientsikkerhed
Consultant Physician, Danish Patient Safety Foundation

Medlemsmøder

Den 15. januar var der medlemsmøde om *'Livscyklusanalyser og fremtidige problematiske stoffer'*. På mødet gav Anthony Abbotts fra Cowi A/S en introduktion til forskellige livscyklusvurderinger og screeningsværktøjer. Derefter gav professor Finn Bro-Rasmussen fra DTU et bud på de fremtidige problematiske stoffer i EU, samt en vurdering af HOT-Spot-analysen og produktvurdering set i lyset af den ny kemikalielovgivning.

Den 25. marts var der *Generalforsamling* i Medicoindustrien. Her fik professor Liselotte Højgaard fra Rigshospitalet og professor Jørgen Arendt Jensen fra Danmarks Tekniske Universitet overrakt Medicoprisen 2004 som tak for deres store engagement omkring både etableringen af den nye uddannelse 'Medicin og Teknologi' og etableringen af MedicoFremtid. Begge initiativer er til stor gavn for den danske medicoindustri.

Professor Liselotte Højgaard, Rigshospitalet/The National Hospital, professor Jørgen Arendt Jensen, Danmarks Tekniske Universitet/The Technical University of Denmark og Mogens Pedersen, formand for Medicoindustrien/ Chairman of Medicoindustrien.

Roger Buch, kommunalforsker ved Syddansk Universitetscenter
Local authority researcher at the University of Southern Denmark

Seminar

On 14 -15 April, a joint seminar for Regional Purchasers (the association of hospital purchasers) and Medicoindustrien gathered nearly 100 participants at Koldingfjord. Consultant Physician Beth Lilja Pedersen from the Danish Patient Safety Foundation talked on patient safety in relation to the procurement of medical devices. In addition, Roger Buch, local authority researcher at the University of Southern Denmark, reviewed the report from the Commission on Administrative Structure and the consequences of its recommendations. Reports were also presented by the joint working groups on issues including the application of the standards for tender procedures and the shared e-commerce project described separately in this Annual Report.

Members' meetings

On 15 January, the first members' meeting of the year focused on *'Life cycle analyses and future substances of high concern'*. Anthony Abbotts from Cowi A/S gave an introduction to various life cycle assessments and screening tools. Professor Finn Bro-Rasmussen from the Technical University of Denmark presented an outline of substances which the EU is expected to classify as substances of high concern and an assessment of the HOT Spot analysis and product assessment in light of the new chemicals legislation.

On 25 March, the General Assembly of Medicoindustrien was held. The Medical Device Award 2004 was presented to Professor Liselotte Højgaard, the National Hospital, and Professor Jørgen Arendt Jensen from the Technical University of Denmark in recognition of their dedication to the introduction of the new degree programme 'Medicine and Technology' as well as the establishment of Medico Future. Both initiatives promise to benefit the Danish medical device industry.

Derefter fortalte Indenrigs- og sundhedsminister Lars Løkke Rasmussen om hans tanker i relation til strukturkommissionens arbejde og den videre reform af det danske sundhedsvæsen.

Den 19. august var der medlemsmøde om *Kina.* På mødet fortalte advokat Johan Løje fra Sandel, Løje & Wallberg om de juridiske forhold ved at etablere produktion i Kina.

Den 9. september var *'Emballage og elektronikaffald'* på dagsordenen. På mødet gav Birgitte Kjær Jørgensen fra Miljøstyrelsen en generel introduktion til emballagedirektivet og de mange tilknyttede standarder. Herefter fortalte Allan Bugge fra Brancheforeningen for Forbrugerelektronik (BFE) om arbejdet med at finde frem til en fælles model for håndtering af elektrisk og elektronisk affald.

Indenrigs- og sundhedsminister Lars Løkke Rasmussen
Minister for the Interior and Health

Den 12. november drejede mødet sig om *'Elektronisk fakturering'*. På mødet fortalte Mikkel Hippe Brun fra IT & Telestyrelsen om de nye krav fra Finansministeriet om elektroniske fakturaer til det offentlige fra den 1. februar 2005. Efterfølgende fortalte konsulent Flemming Beltoft fra MySupply, hvordan de nye krav harmonerer med Medicoprojektet.

Erfaringsudveksling

Det har været et mål for Medicoindustrien, at 2/3 af medlemsvirksomhederne var aktive i udvalg og erfa-grupper - jo mere aktive virksomhederne er, jo bedre bliver organisationen. Det mål er nået! I 2004 var 68% af medlemsvirksomhederne med i udvalg og erfa-grupper. 91% af virksomhederne deltog i en eller anden form for aktivitet i organisationen dvs. medlemsmøder, kurser, generalforsamling eller udvalg og erfa-grupper. Det er vi meget godt tilfredse med.

Medicoindustrien har 9 udvalg og 10 erfa-grupper. Der er i alt 122 udvalgsmedlemmer og 85 medlemmer af vores erfa-grupper. Forskellen på et udvalg og en erfa-gruppe er, at udvalgene står i tæt kontakt med sekretariatet, idet de udgør en meget væsentlig del af organisationens faglige ekspertise og står til rådighed i forbindelse med f.eks. afgivelse af høringssvar til myndighederne.

Next, the Minister for the Interior and Health, Lars Løkke Rasmussen, reflected on the work of the Commission on Administrative Structure and the ensuing reform of the Danish healthcare service.

On 19 August, members were invited to a meeting about *China*. Attorney Johan Løje from Sandel, Løje & Wallberg talked about the legal implications of setting up manufacturing activities in China.

On 9 September, the agenda featured *'Packaging and electronic waste'*. Birgitte Kjær Jørgensen from the Environmental Agency gave a general introduction to the packaging directive and the many associated standards. Next, Allan Bugge from BFE, the Industry Association for Consumer Electronics, talked about the initiative to develop a common model for handling electrical and electronic waste.

On 12 November, the meeting topic was *'Electronic invoicing'*. Mikkel Hippe Brun from the IT & Telecom Agency presented the new requirements from the Ministry of Finance, stipulating that all invoices to the public sector must be in an electronic format as from 1 February 2005. In addition, Consultant Flemming Beltoft from MySupply described how the new requirement will harmonise with the Medical Device Project.

Sharing experience

Since the strength of our organisation depends on active members, Medicoindustrien has had a long-standing goal to get two-thirds of all member companies involved in the work of our committees and groups set up for exchange of experience. We have now attained that goal! In 2004, 68 % of all member companies had representatives on committees and experience groups and 91 % of all companies took part in some form of activity under the auspices of the association, either members' meetings, courses, the General Assembly or committees or experience groups. We find this high rate satisfactory indeed.

Erfa-grupperne er derimod udelukkende diskussions- og erfaringsudvekslingsfora. I det følgende vil der derfor kun være rapporter fra de 9 udvalg.

Lovgivningsudvalget

Revisionen af direktivet for medicinsk udstyr
Udvalget har fulgt revisionen af direktivet for medicinsk udstyr. Der hersker umiddelbart stor tilfredshed blandt såvel myndigheder som producenter med det nuværende godkendelsessystem. Der har dog været forskellige forslag fremme til ændring af direktivet, og dem har lovgivningsudvalget fulgt og kommenteret. I efteråret 2004 kom Kommissionen så med et forslag til revisionen af direktivet. Der er tale om mindre justeringer, hvilket Medicoindustrien er godt tilfreds med.

Revisionen af lægemiddeldirektivet
Efter vedtagelsen af det nye lægemiddeldirektiv i foråret 2004 gik Kommissionen i dialog med medicoindustrien og de andre industrier, der grænser op til lægemiddelområdet. Baggrunden for dialogen er, at det nye lægemiddeldirektiv indeholder en bestemmelse, der giver lægemiddelreglerne forrang, såfremt der er tvivl om, hvorvidt et produkt hører under det ene eller andet regelsæt. Myndighederne har ved flere lejligheder tilkendegivet, at de ikke ønsker at flytte den nuværende grænse mellem lægemiddelreglerne og reglerne for godkendelse af medicinsk udstyr. De forsøger blot at fremtidssikre godkendelsessystemerne til de nye produkter, som kommer i grænseområdet mellem blandt andet lægemidler og biotek. Dialogen foregår i en arbejdsgruppe, som Kommissionen har nedsat. Deres arbejde følger lovgivningsudvalget via sin repræsentation i EUCOMED's arbejdsgruppe om grænseprodukter og opklassificeringer.

Kvalitetssikringsudvalget

Ændringer i lovgivningen
Kvalitetssikringsudvalget har fulgt de forslag, der er kommet om ændringer i direktiverne om medicinsk udstyr og har diskuteret, hvilke konsekvenser ændringerne kan have for de danske producenter. Udvalgets ønske om at fjerne nummeret på det godkendelsesorgan, som har godkendt produktet fra mærkningen, er desværre ikke blevet hørt.

Derudover har udvalget gennemgået ændringerne i den japanske og australske lovgivning og påskønner, at disse lande også anvender ISO 13485 som baggrund for kravene til kvalitetsstyring.

Standarder og samarbejdet med DS
Udvalget har drøftet flere nye standarder, og hvordan de bedst implementeres.

Medicoindustrien has nine standing committees and 10 groups set up for exchange of experience. Total committee membership is 122, while groups set up for exchange of experience have 85 members in all. Committees are distinguished from experience groups by having closer links with the secretariat. The committees represent a significant part of the association's expertise resources and may be called in to offer assistance, such as for submitting consultation response to authorities. Groups set up for exchange of experience, in contrast, are exclusively fora for discussion and experience sharing. The following reports are therefore from the nine committees alone.

Legal and Regulatory Affairs Committee

Revision of the medical devices directive
The committee followed the revision of the medical devices directive over the year. In general, both authorities and manufacturers find the existing approval system fully satisfactory. However, a variety of proposals to amend the directive had been put forward, and the committee considered them and submitted comments. In the autumn of 2004 the Commission finally introduced its proposal to revise the directive, and Medicoindustrien was pleased to note that it included only minor adjustments.

Revision of the medicinal products directive
After the adoption of the new medicinal products directive in spring 2004, the Commission engaged in dialogue with the medical device industry and the other industries adjacent to the pharmaceutical area. What spurred the dialogue was a new provision in the medicinal products directive giving the medicinal products rules priority in case of doubt as to whether a product should be governed by one rule set or the other. The authorities had indicated on several occasions that they did not intend to shift the existing boundary between the medicinal products rules and those governing the approval of medical devices. The aim is only to ensure that the approval systems are geared to handle new products that may be introduced in the borderland between drugs and biotech products. Dialogue is being conducted in a working group appointed by the Commission. The Legal and Regulatory Affairs Committee keeps track of this work via its representative on the EUCOMED Task Force on Classification and Borderline Products.

Quality Assurance Committee

Changed legislation
In the past year, the Quality Assurance Committee followed the proposals to amend the directives on medical devices and discussed their potential consequences for Danish manufacturers. The committee had called for removal of the ID number of the notified body approving the product from product labelling, but the proposal was unsuccessful.

In addition, the committee reviewed recent amendments to the Japanese and Australian legislation, noting with satisfaction that

ISO 13485:2003 Kvalitetsstyringsstandarden for medicoindustrien og den tilhørende vejledning ISO 14969 er nu trådt i kraft. Det er diskuteret i udvalget, hvordan disse standarder, sammen med standarden for risikostyring og »Usability« standarden, kan blive en naturlig del af virksomhedernes kvalitetsstyringssystemer. Samarbejdet mellem Medicoindustrien og Dansk Standard er desværre ophørt, da det blev for dyrt. Det har dog ikke betydet, at der har været problemer med at følge med i standardiseringsarbejdet, da vi har kunnet følge det via vores europæiske organisation EUCOMED.

Udvalget for klinisk afprøvning og biosikkerhed

Udvalget fortsatte i 2004 arbejdet med revisionen af de primære standarder for kliniske afprøvninger (ISO/EN 14155) og biosikkerhed (ISO 10993). Derudover udarbejdede udvalget en liste over relevante kontrakthuse samt en introduktion til, hvordan kliniske afprøvninger foretages.

Udvalget stod for afviklingen af kurserne 'Biocompatibility testing and management' og 'Kritisk litteraturvurdering'.

I september blev det besluttet at dele udvalget i to, idet kliniske afprøvninger og biologiske evalueringer grundlæggende er to forskellige discipliner.

Sterilisationsudvalget

Der arbejdes fortsat intenst i internationalt regi på harmoniseringen af standarderne for sterilisation. Sterilisationsudvalget diskuterer, som fast punkt på dagsordenen for deres møder, udviklingen omkring disse standarder. Sterilisationsudvalget har foretaget en grundig gennemgang af udkastene, og ser nu med forventning frem til selve færdiggørelsen og den efterfølgende implementering af standarderne. Harmoniseringsarbejdet er nu så langt, at de færdige standarder forhåbentligt vil være godkendt inden for de næste par år.

the two countries also use ISO 13485 as the cornerstone of their quality management requirements.

Standards and collaboration with the Danish Standards Association

In 2004, the committee discussed several new standards and how best to implement them.

ISO 13485:2003, the quality management standard for the medical device industry, and the associated ISO 14969 guidelines have now entered into force. The commitee discussed how these standards, along with the risk management standard and the usability standard, can be integrated naturally into the quality management systems of companies.

Unfortunately, the collaboration between Medicoindustrien and the Danish Standards Association came to an end because of the cost. However, we have been able to follow the progress of ongoing standardisation work through our European organisation, EUCOMED.

Committee on Clinical Trials and Biocompatibility

In 2004, the committee continued its work related to the revision of the primary standards for clinical trials (ISO/EN 14155) and biocompatibility (ISO 10993). The committee also drew up a list of relevant contract houses and an introduction to how clinical trials are carried out.

The committee organised and held courses on 'Biocompatibility Testing and Management' and 'Critical Literature Evaluation'.

In September, the decision was made to split the committee in two, recognising that clinical trials and biological evaluation are essentially two distinct disciplines.

Resterilisering af engangsudstyr har været et meget aktuelt emne på flere af møderne. Udviklingen på dette område følges nøje og med en del bekymring.

Desværre har der ikke været nogen udvikling vedr. området for LAL-test og barrieretest af pakninger, men udvalget vil tage enhver udvikling på områderne op til diskussion.

Med hensyn til undervisning så har flere af udvalgets medlemmer deltaget aktivt som undervisere på introduktionskurset. Det planlagte kursus vedr. sterilisation og materialeegenskaber måtte desværre aflyses pga. for få tilmeldinger. Da der fortsat kommer tilbagemeldinger fra medlemsvirksomhederne om et behov for kurser relateret til sterilisation, vil udvalget forsøge at sammensætte et nyt kursus i efteråret 2005.

Renrum
De harmoniserede standardserier for renrum, ISO 14644 og ISO 14698, er næsten alle godkendt. De enkelte virksomheder er i fuld gang med implementeringen af standarderne, og gruppen for renrum diskuterer løbende praktiske problemstillinger og tolkninger.

Teknologiudvalget

Kontakt til universiteter
Udvalget har haft nogle konstruktive møder med Danmarks Farmaceutiske Universitet for at få gjort medicoindustrien mere synlig overfor de studerende og for at sikre, at nogle af de kompetencer, som medicoindustrien har behov for, tilbydes på uddannelserne.

Udvalget er repræsenteret i referencegruppen for Danmarks Tekniske Universitets og Københavns Universitets nye medicocivilingeniøruddannelse 'Medicin og Teknologi'. Formålet er at være med til at designe uddannelsen, således at medicoindustrien kan få glæde af kandidaterne.

Kompetenceudvikling
Medicoindustrien har indgået et samarbejde med Aalborg Universitets kompetenceudviklingscenter ELITE, der har igangsat et forskningsbaseret projekt om at udvikle et analyseredskab til konkretisering af kompetencebehov.

Udvalget har også haft møder med erhvervsskolen Hamlet, som har indgået et samarbejde med nogle amerikanske og en irsk erhvervsskole om kompetenceudvikling indenfor medicosektoren.

Forskning
Udvalget har fulgt og kommenteret Risø's oplæg til ny strategi som blandt andet indebærer, at der er udpeget tre forskningstemaer indenfor bio- og medicoteknik.

Sterilisation Committee

Work to harmonise the standards for sterilisation continues to require concentrated effort at the international level. Thus, a permanent item on the agenda of the Sterilisation Committee is discussing developments in the drafting of these standards. In the past year, the committee reviewed these drafts thoroughly and now looks greatly forward to the final completion and subsequent implementation of the standards. The harmonisation process has advanced to a point that makes it realistic to expect adoption of the final standards within the next couple of years.

Developments in the area of resterilisation of single-use devices, a hot topic at several meetings of the committee, are monitored carefully and with a good deal of concern.
There was, unfortunately, no progress in the area of LAL tests and barrier testing of packaging, but the committee will address and discuss any new developments.

Regarding teaching, several members of the committee served as teachers on the introduction course. However, the planned course on Sterilisation and Materials Properties had to be cancelled due to insufficient interest. Since we still receive feedback from member companies that need courses related to sterilisation, the committee will try to develop a new course for the autumn 2005 programme.

Clean rooms
Almost all standards in the harmonised clean room series, ISO 14644 and ISO 14698, have been adopted and the companies affected are in full swing implementing them. Thus, the clean room group discusses practical issues and interpretations on an ongoing basis.

Technology Committee

Contact to universities
In 2004, the committee had several constructive meetings with The Danish University of Pharmaceutical Science aimed to make the medical device industry more visible to their students and ensure that some of the skills required by medical device manufacturers will be integrated in the university's degree programmes. The committee is represented on the reference group for the new medical engineering degree programme of the Technical University of Denmark and the University of Copenhagen, 'Medicine and Technology'. The objective is to put our fingerprint on the programme design, ensuring recruitment potential for the medical device industry.

Skills development
Medicoindustrien has entered into collaboration with Aalborg University's skills development centre, ELITE, which has launched a research project to develop an analysis tool for mapping out skills requirements.

For at opnå større indsigt i, hvad der driver innovation, og hvilke rammebetingelser virksomhedernes innovation baserer sig på, har Danmarks Erhvervsråd og Økonomi- og Erhvervsministeriet igangsat analyser af innovation i fire toneangivende brancher i Danmark. Medicobranchen er en af de udvalgte brancher.

Undersøgelsen af innovation i medicobranchen udføres af FORA og Erhvervs- og Boligstyrelsen i samarbejde med Medicoindustrien.

Medicoinnovation
Teknologiudvalget fungerer som sparringspartner for sekretariatet i forbindelse med udarbejdelse af ideoplæg til Medicoindustriens innovationscenter.

Miljøudvalget

Markedsrettet miljøinformation
Udvalget har løbende udvekslet erfaringer mht. amternes implementering af danske produktdatablade, samt givet input til Medicoindustriens vejledning omkring udfyldelse af miljødelen i produktdatabladet.

Spørgeskemaundersøgelse om miljøledelse
Udvalget har gennemført en spørgeskemaundersøgelse blandt Medicoindustriens producerende medlemsvirksomheder om udbredelsen af miljøledelse. Målet med undersøgelsen var at sammenligne danske medicovirksomheders indsats på miljøområdet med medicoindustrien i resten af Europa for udpegning af fremtidige indsatsområder. Desværre blev der modtaget for få besvarelser fra medlemsvirksomheder, hvorfor det ikke var muligt at evaluere branchens miljøindsats.

Overvågning af regler og nye tiltag
Via EUCOMED har udvalget holdt sig orienteret om nye EU-miljølovgivningstiltag. Udvalget har løbende fulgt fortolkningen og implementeringen af det reviderede emballagedirektiv samt af direktivet om elektronisk og elektrisk affald. Der er i efteråret 2004 blevet afholdt et medlemsmøde om implementering af de ovennævnte direktiver.

Udvalget har løbende ajourført en liste over relevante miljøstandarder for medicoindustrien, opdateret faktablade og fulgt udviklingen med hensyn til, hvilke stoffer der anses for uønskede i medicinsk udstyr. Der er i januar 2004 blevet afholdt et medlemsmøde om fremtidige problematiske stoffer i medicinsk udstyr.

In addition, the committee has held meetings with Hamlet Technical College, which has forged collaborative links with a couple of colleges in the USA and one in Ireland on skills development for the medical device and technology sector.

Research
The committee has followed and presented comments on the new draft strategy for Risø National Laboratory, which includes three research themes in the field of medical and bio-technology.

To gain greater insight into what drives innovation and the types of framework that underpin corporate innovation, the Danish Council for Trade and Industry and the Ministry of Economic and Business Affairs have launched a process to analyse innovation in four trend-setting sectors of Danish industry. The medical device sector is one of them.

The analysis of medical device innovation is conducted by the FORA research centre and the National Agency for Enterprise and Construction in collaboration with Medicoindustrien.

Medical technology innovation
The Technology Committee also acts as a sparring partner to the secretariat in its preparation of draft policy papers for Medicoindustrien's innovation centre.

Environmental Committee

Market-oriented environmental information
In the past year, the committee engaged in ongoing exchange of experience concerning the regional purchasers' implementation of Danish product data sheets and provided input to Medicoindustrien's guidelines on how to fill in the environmental fields of the data sheet.

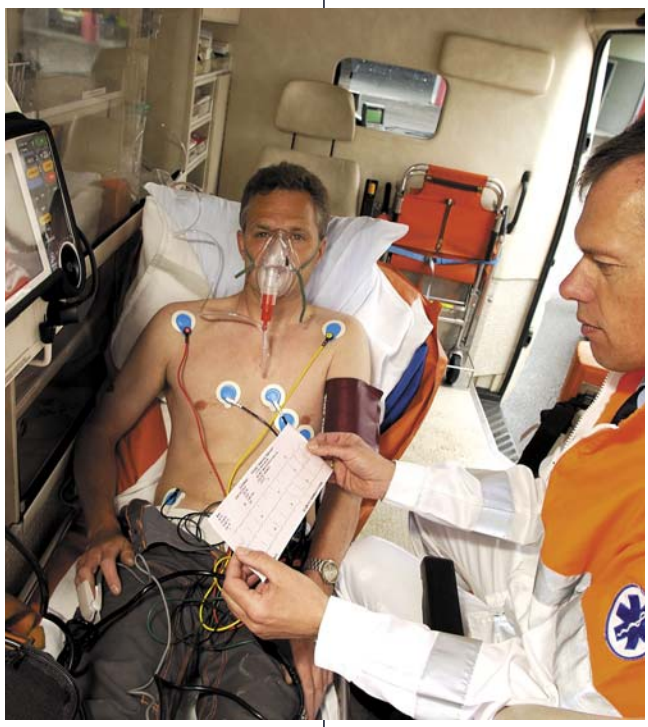
Questionnaire survey of environmental management
The committee launched a questionnaire survey on the rate of introduction of environmental management systems by the manufacturing members of Medicoindustrien. The objective was to compare the environmental performance of Danish medical device manufacturers to that of the medical device industry in the rest of Europe, and pinpoint areas for future action. However, the committee did not receive enough replies from members to allow an evaluation of our industry's environmental performance.

Monitoring rules and new initiatives
The committee kept posted about new EU environmental legislation initiatives through EUCOMED. In addition, the committee monitored the interpretation and implementation of the revised packaging directive as well as the directive on electrical and electronic waste. In late 2004, the committee invited members to a meeting about the implementation of the two directives.

Kapitalvareudvalget

Samarbejde med medicotekniske afdelinger
Medicoindustrien har haft to møder med erfa-gruppen for medicotekniske chefer i 2004. På møderne har følgende emner været drøftet: Manglende tid til uddannelse af brugerne i udstyret på sygehusene, kravspecifikationer og bevillingsmæssig dækning i forbindelse med udbud af kapitalvarer og service af udstyret, herunder mulighederne for at yde remote service.

Medicoindustrien har i årets løb fået to repræsentanter i bestyrelsen for Dansk Medicoteknisk Selskab.



Standardkravspecifikationer for visse produkter
Der er i dag meget stor forskel på indholdet i de krav-specifikationer, der opstilles i amterne i forbindelse med EU-udbud af kapitalvarer. Tendensen går imod mere og mere detaljerede specifikationer og spørgsmål. Omfanget af tilbuds-arbejdet tiltager derfor i en sådan grad, at det i visse tilfælde ikke vil være attraktivt at afgive et tilbud. Udvalget arbejder derfor for at påvirke sygehusene til at udarbejde funktionskrav i stedet for de detaljerede kravspecifikationer.

Forbrugsvareudvalget

Udbud
Udvalget overvåger brugen af de fælles udbudsstandarder, som 'Regionale Indkøbere' og Medicoindustrien sammen har udarbejdet for at optimere samhandlen. Der er stadig stor fokus på, i hvor høj grad amterne anvender dem.

Udvalget har også diskuteret en række konkrete udbud. I flere tilfælde har dette ført til henvendelser fra Medicoindustrien, som har medført, at indkøberen har rettet op på de ting, som udvalget har påpeget. I 2004 har der også været et par konkrete klagesager, hvor Konkurrencestyrelsen i kølvandet på Medicoindustriens klager har rådet ordregiveren til at annullere udbuddet. Endelig har udvalget initieret et kursus om de nye udbudsregler, der trådte i kraft den 1. december 2004.

The committee continually updated a list of environmental standards relevant to the medical device industry, revised fact sheets and followed development trends in relation to substances viewed as undesirable in medical devices. In January 2004, the committee organised a members' meeting about substances of high concern in future medical devices.

Capital Goods Committee

Collaboration with medical technology departments
Medicoindustrien held two meetings with the forum of medical technology managers in 2004 to discuss a range of issues including: Insufficient time to train operators of equipment at hospitals, requirement specifications, funding appropriations in connection with capital goods procurement and servicing of equipment, for example access to providing remote service.

In the course of the year, Medicoindustrien was able to appoint two representatives to the board of the Danish Society for Medical Technology.

Standardised requirement specifications for certain products
Today, the requirement specifications defined by regional authorities in connection with their capital goods procurement under the EU rules vary considerably in content and tend to be increasingly detailed. The workload involved in preparing tenders is consequently growing to such an extent that submitting a tender is highly unattractive in some cases. The committee is therefore seeking to persuade hospitals to draw up functional requirements rather than detailed requirement specifications.

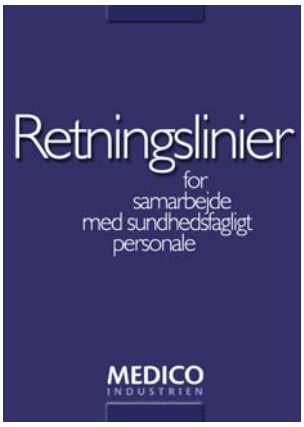
Medical Disposables Committee

Tender procedures
The committee keeps a close watch on the use of the common standards for public tenders drafted jointly by Regional Purchasers and Medicoindustrien to optimise the trading process. The key focus is still on whether the regional purchasers use them and how much.

Det danske marked i fremtiden
Udvalget har også fokus på fremtidens danske marked. Medicoindustrien arbejder blandt andet på at synliggøre distributørernes rolle i det danske sundhedsvæsen. Den fremtidige struktur har ligeledes været et vigtigt emne, da det får store konsekvenser for leverandørerne. Derudover har problemstillingen med amters videresalg til lægepraksis været drøftet, og der har været korresponderet med Konkurrencestyrelsen og Indenrigsministeriet om sagen.

Genbrug
Mange udvalgsmedlemmer er berørt af genbrugssagen og har derfor fulgt genbrugsdebatten tæt. De fleste udvalgsmedlemmer deltog da også i Medicoindustriens høring om genbrug i februar måned.

Sponsorering
Julen 2004 blev første jul med Medicoindustriens 'Etiske retningslinier for samarbejde med sundhedspersonale'. Det gav anledning til en livlig debat om fortolkningen af begrebet 'beskedne gaver'. Mange virksomheder plejer at give deres samarbejdspartnere julegaver. Det er en hyggelig tradition, som kan være svær at bryde, men virksomhederne skal tænke sig godt om. Ifølge retningslinierne kan der gives beskedne gaver til sundhedsfagligt personale, men de skal være af begrænset værdi, og som regel bør gaverne være til gavn for patienterne eller have et egentligt uddannelsesmæssigt formål. Det kan selvfølgelig diskuteres, hvad der kan betegnes som beskedne gaver. Sekretariatet rådede imidlertid medlemmerne til at stoppe deres praksis med at give eksempelvis rødvin og skjorter til samarbejdspartnerne ved juletid. Samarbejdet må på ingen måde kunne mistænkeliggøres – dertil er det alt for vigtigt.



E-handelsudvalget

E-handelsudvalget består af repræsentanter fra de 39 virksomheder, der deltager i Medicoprojektet. Læs om selve projektet ovenfor. Udvalget har fungeret som erfaringsudvekslingsforum for deltagerne og som forum for dannelse af Medicoindustriens holdninger til projektet.

The committee also considered a number of specific tendering procedures in 2004. In several cases Medicoindustrien had to write letters to purchasers, after which they corrected the serious flaws the committee had pinpointed. The year also saw a few concrete complaints from Medicoindustrien to the Competition Authority, prompting the Authority to advise the contracting purchasers to cancel their procedures. In addition, the committee organised a course on the new procurement rules that entered into force on 1 December 2004.

Future of the Danish market
The focus of the committee is also on the future of the Danish market. Among other initiatives, Medicoindustrien seeks to enhance recognition of the distributors' role in the Danish health service. The future administrative structure was also an important topic, given the extensive consequences it will have for all suppliers. In addition, the regional authorities' resale of products to the general practice sector was discussed, and Medicoindustrien exchanged correspondence with the Competition Authority and the Ministry of the Interior about the issue.

Reuse
Many members of the committee are affected by the reuse issue and follow the reuse debate closely. Thus, most members of the committee attended Medicoindustrien's reuse hearing in February 2004.

Sponsoring
Christmas season 2004, the first with Medicoindustrien's Code of Ethics for Interactions with Healthcare Professionals, produced lively debate on the interpretation of the concept of 'modest gifts'. Many companies are accustomed to giving their collaboration partners Christmas presents, which is a nice tradition. However, the tradition can be hard to break and companies now have to think twice about the practice. Adhering to the Code of Ethics, members may offer modest gifts to healthcare professionals. However, modest means of marginal value and the gifts should ordinarily benefit patients or take an educational form. What can be characterised as a modest gift is debatable, of course. However, the secretariat advised members to put an end to the practice of giving gifts like red wine or shirts to collaboration partners in the Christmas season. A collaborative relationship must in no way give rise to any hint of suspicion – it is far too important for that.

E-commerce Committee

The committee consists of representatives from the 39 companies that take part in the Medical Device Project, described elsewhere in this Annual Report. The committee has given members opportunities to share experience and acted as the forum defining Medicoindustrien's position on the project.

Uddannelse

Det fjerde punkt i Medicoindustriens idegrundlag er, at organisationen skal være det naturlige sted for uddannelse og kompetenceudvikling i branchen.

Mange af Medicoindustriens kurser udspringer af aktiviteterne i de mange udvalg og erfa-grupper, ligesom mange af underviserne kommer derfra. Undervisernes store engagement og faglige indsigt er medvirkende til, at kursusudbuddet hvert år er så omfangsrigt, som det er. Den kendsgerning, at de interne undervisere ikke får honorar, betyder, at deltagergebyret kan holdes på et niveau, som ofte kun er halvdelen af, hvad tilsvarende faglige kurser koster hos andre kursusudbydere.

I 2004 udbød Medicoindustriens 'Institut for Uddannelse' 23 kurser, hvoraf 19 blev gennemført. På kurserne deltog i alt 352 medarbejdere fra 50 af organisationernes medlemsvirksomheder, hvilket vil sige, at 57% af virksomhederne benytter sig af kursustilbuddene. En tilfredshedshedsmåling i oktober måned viste, at medlemmerne bliver mere og mere tilfredse med kursusaktiviteterne. Vi bestræber os på hele tiden at udvikle kursusaktiviteterne, så vi dækker de behov, der opstår hos virksomhederne og inddrager nye målgrupper, efterhånden som vi får kendskab til uddannelsesbehovene.

Kursusaktiviteter 2004

Softwarevalidering den 3. februar
Formålet med dette kursus var at give deltagerne et indblik i de myndighedskrav der stilles til softwarevalidering, og samtidig sætte deltagerne i stand til at gennemføre valideringer af det software, der anvendes i medicinsk udstyr, eller udstyr der anvendes til udvikling og produktion af medicinsk udstyr.

Hygiejnekrav den 25. februar
På dette kursus blev der sat fokus på hygiejnekrav i forbindelse med produktion af medicinsk udstyr i renrum, dvs. klassificering, måling og dokumentation, samt renrumsbeklædning. Derudover blev der undervist i bioburden i forhold til sterilisationsprocesser.

Risk Management i relation til medicinsk udstyr den 3. – 4. marts
Med udgangspunkt i Risk Management standarden ISO 14971 fik deltagerne et detaljeret kendskab til de krav og teknikker, der benyttes ved risikoanalyser.

Medicoteknisk oversættelse den 17. – 18. marts
På dette kursus blev der sat fokus på medicotekniske oversættelser. Deltagerne fik viden om branchens sprogtermer, og de fik færdigheder til at analysere og producere professionelle tekster på engelsk.

Training

The fourth element of Medicoindustrien's strategic business concept is establishing the association as the natural provider of training and skills development for the industry.

Many courses offered by Medicoindustrien spring from the activities of our committees and groups set up for exchange of experience, from which many course teachers are recruited as well. Their dedication and expertise underpin the broad course programme we offer every year. Since 'internal' teachers receive no remuneration we are able to keep course fees at a level that is often just half the price of similar courses offered by external providers.

In 2004, Medicoindustrien's Institute for Education planned 23 courses and held 19 of them. A total of 352 staff members from 50 of the association's member companies participated or, in other words, 57 % of all members take advantage of the course programme. A satisfaction survey conducted in October 2004 showed increasing appreciation of our course activities among member companies. We strive continually to develop courses that meet the needs of our members and include new target groups once we learn their training requirements.

Course activities 2004

Software Validation, 3 February
The objective of this course was to give participants an insight into the regulatory requirements imposed on software validation, enabling them to carry through validation of software integrated in medical devices or in equipment used to develop and manufacture medical devices.

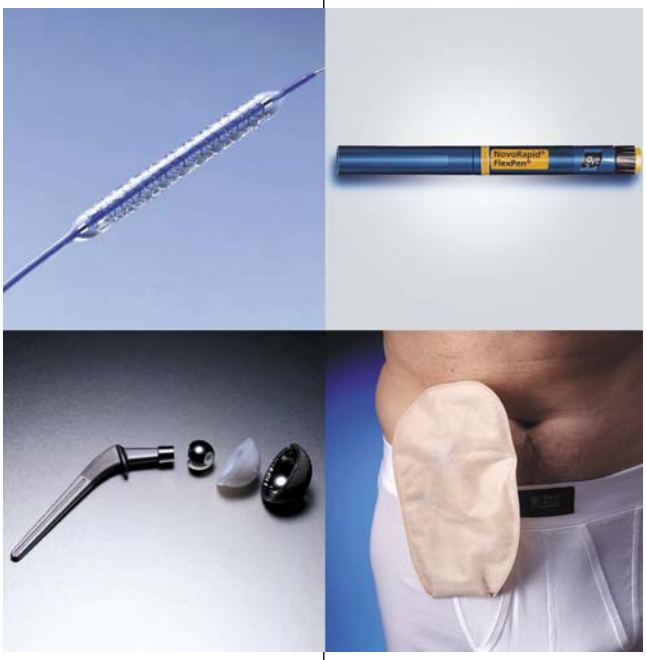
Hygienic Requirements, 25 February
This course focused on the hygienic requirements associated with the production of medical devices in clean rooms, including classification, measuring, documentation and clean room clothing. The course also addressed bioburden in relation to sterilisation processes.

Risk Management in relation to Medical Devices, 3 – 4 March
Based on the risk management standard, ISO 14971, the participants were given in-depth insight into the requirements and techniques of risk analysis.

Medical Device Translation, 17 – 18 March
The focus of this course was translation in the context of medical devices. The participants were introduced to industry-specific terminology and trained in analysing and producing professional texts in English.

Introduktionskursus til medicobranchen den 30. marts - 1. april
Kurset giver på 3 dage en indføring i medicobranchen og en bred forståelse for de metoder, relationer og lovkrav, der er essentielle for medarbejdere i branchen.

Procesvalidering den 10. maj
Da der havde vist sig et stort behov for endnu et kursus i procesvalidering, kom vores amerikanske underviser Anita Thibeault på en ekstra tur til Danmark. Kurset giver deltagerne en indføring i, hvordan de kan optimere deres processer og skabe en stabil kvalitet.



Reklameregler for medicinsk udstyr den 27. maj
Undervisere fra Lægemiddelstyrelsen fortalte på kurset om de regler der gælder, når man skal reklamere for medicinsk udstyr overfor patienterne og overfor professionelle brugere og indkøbere. Derudover blev Medicoindustriens retningslinier for samarbejde med sundhedsfagligt personale gennemgået.

Biosikkerhed den 24. – 25. juni
Dr. Nancy J. Stark fra USA underviste på kurset i biosikkerhed. Kurset gav deltagerne viden om, hvordan man udarbejder en struktureret biologisk evaluering.

Introduktion til anatomi og fysiologi den 30. – 31. august
Kurset gav deltagerne et indblik i menneskets opbygning og funktion.

EU's godkendelsesregler for medicinsk udstyr den 13. september
Kurset gav et grundigt kendskab til og forståelse for EU's godkendelsesregler for medicinsk udstyr.

Quality Assurance in Product Development den 27. – 28. september
Den sidste uge i september underviste Anita Thibeault fra USA i kvalitetssikring i forbindelse med produktudvikling. Hun gennemgik således aktiviteterne i en udviklingsproces og satte fokus på prioritering og sikring af den bedst mulige proces og overensstemmelse med lovgivning.

Introduction to the Medical Device Industry, 30 March – 1 April
The three-day course provided an introduction to the industry and broad understanding of the methods, relations and regulatory requirements essential to staff employed in the medical device industry.

Process Validation, 10 May
Our American instructor, Anita Thibeault, came to Denmark an extra time after we registered keen demand for one more course on process validation. The course gives participants basic knowledge on how to optimise their processes and ensure quality stability.

Rules for Medical Device Advertising, 27 May
Course teachers from the Medicines Agency presented the rules applying to advertising medical devices to both patients and professional users and purchasers. Medicoindustrien's Code of Ethics for Interactions with Healthcare Professionals was also reviewed.

Biocompatibility, 24 – 25 June
Dr. Nancy J. Stark from the USA taught the course on biocompatibility, offering participants knowledge on how to prepare structured biological evaluations.

Introduction to Anatomy and Physiology, 30 – 31 August
The course provided participants with insight into the structure and functions of the human body.

The EU Certification Rules for Medical Devices, 13 September
The course gave in-depth knowledge and understanding of the EU rules governing the certification of medical devices.

Quality Assurance in Product Development, 27 – 28 September
The last week in September, Anita Thibeault from the USA taught quality assurance related to product development, reviewing the activities of the R&D process with focus on priorities and assurance of the optimum process and conformity with current legislation.

Procesvalidering den 30. september
Kurset blev igen afholdt med fuldt hold og gav deltagerne en indføring i, hvordan de kan optimere deres processer og skabe en stabil kvalitet.

Introduktion til anatomi og fysiologi den 4. – 5. oktober
Kurset gav deltagerne et indblik i menneskets opbygning og funktion.

Prækvalifikation og tilbudsskrivning den 19. oktober
Kurset tog udgangspunkt i praktiske problemstillinger i forbindelse med prækvalifikation og tilbudsgivning. Herunder hvad der kræves i forbindelse med prækvalifikation og hvilke udfordringer og faldgrubber, der er i forbindelse med tilbudsskrivning.

Introduktionskursus til medicobranchen den 9. – 11. november
Kurset giver på 3 dage indsigt i medicobranchen og en bred forståelse for de metoder, relationer og lovkrav, der er essentielle for medarbejdere i branchen.

EU's nye udbudsregler den 17. november
Formålet med kurset er at give deltagerne en indføring i EU's nye udbudsdirektiv, herunder de væsentligste ændringer i det nye direktiv, der er trådt i kraft den 1. januar 2005.

Introduktion til AMKAT den 17. – 18. november
Medicoindustrien har i samarbejde med Amtsrådsforeningen gennemført et E-handelsprojektet, som omtalt under afsnittet 'Gennembrud for elektronisk handel med amterne'. E-handelskataloget blev åbnet for alle virksomheder, da projektet sluttede. Derfor gennemførte vi et kursus, som var en grundig introduktion til, hvordan man arbejder med E-kataloget. På kurset deltog også nye medarbejdere fra de virksomheder, der var en del af projektet.

Kritisk Litteraturvurdering den 19. november
Deltagerne fik indsigt i at vurdere kvaliteten af artikler og have en overordnet forståelse af de krav, der stilles til litteraturgennemgang i forbindelse med at opnå godkendelse af medicinsk udstyr.

Undervisningsteknik den 30. november – 1. december
Medicoindustrien afholder nogle meget intensive kurser i undervisnings- og præsentationsteknik. Deltagerne får lejlighed til selv at træne deres undervisning, som bliver optaget på video. Efterfølgende får de en personlig tilbagemelding, krydret med konkrete og konstruktive råd, så deltagerne lærer at målrette deres undervisning ved at inddrage forskellige pædagogiske hjælpemidler.

Process Validation, 30 September
This was a repeat course, held with a full class, giving participants basic knowledge on how to optimise their processes and ensure quality stability.

Introduction to Anatomy and Physiology, 4 – 5 October
The course provided participants with insight into the structure and functions of the human body.

Prequalification and Preparing Tenders, 19 October:
The course, which focused on the practical problems associated with prequalification and preparing tenders, reviewed the requirements for prequalification and the challenges and pitfalls to watch out for when writing tenders.

Introduction to the Medical Device Industry, 9 – 11 November
The three-day course provided an introduction to the industry and broad understanding of the methods, relations and regulatory requirements essential to staff employed in the medical device industry.

The New EU Procurement Rules, 17 November
The objective of the course was to give participants insight into the new procurement directive, including the most significant amendments to the directive, which entered into force on 1 January 2005.

Introduction of AMKAT, 17 – 18 November
Medicoindustrien has carried out a E-commerce Project in collaboration with Danish Regions, as described in the section headed 'Breakthrough for Electronic commerce with regional authorities'. The e-commerce catalogue was opened to all companies when the project was completed and thus we held this course as an introduction on how to work with the e-commerce catalogue. Participants included new staff from the companies participating in the project.

Critical Literature Evaluation, 19 November
Participants were schooled in assessing the quality of articles and acquiring an overall understanding of the literature review requirements made in conjunction with certification of medical devices.

Teaching and Instruction Skills, 30 November - 1 December
Medicoindustrien offers intensive courses in teaching, instruction and presentational skills. Participants are given the opportunity to hone their skills by making a presentation that is video taped and followed by individualised feedback and specific, constructive advice. Thus, they learn to target their teaching by integrating a variety of educational aids.

The Medical Device Sales Consultant Programme

2004 marked the launch of the new programme for sales and marketing staff, with 15 students joining the pilot class in Janu-

Medicokonsulentuddannelsen

2004 blev også året, hvor vi fik startet den nye uddannelse for salgs- og marketingfolk. 15 startede på pilotholdet i januar måned. 4 af de 6 moduler blev gennemført i årets løb, resten gennemføres i 2005. De første medicokonsulenter springer ud i juni 2005. Uddannelsen er omtalt i et særskilt afsnit andetsteds i beretningen.

Offentligt-privat samspil

Medicoindustrien har tæt kontakt til dem, der regulerer, bruger og indkøber medicinsk udstyr. Vi har også god kontakt til de relevante uddannelsesinstitutioner og myndigheder, der er af betydning for de rammevilkår, som medicovirksomhederne skal leve under.

De regulerende myndigheder
Sekretariatet er i jævnlig kontakt med de ansatte i Lægemiddelstyrelsen og i Sundhedsstyrelsen, både for så vidt angår konkrete sager, men også i forbindelse med begge styrelsers undervisning på Medicoindustriens kurser. Herudover mødtes Medicoindustriens bestyrelse den 16. april 2004 med Lægemiddelstyrelsens direktion til et uformelt møde, hvor der blev drøftet sager af fælles interesse.

Brugerne af medicinsk udstyr
Medicoindustrien har været medstifter af 'Dansk Selskab for Patientsikkerhed' og er aktiv deltager i såvel bestyrelsen som forretningsudvalget. Det kan ikke undgås, at der sker fejl med medicinsk udstyr, men det skal så vidt muligt forebygges, at samme fejl sker mere end en gang. Det er den fælles interesse som behandlere, patienter og virksomhederne har. Adskillige af Medicoindustriens medlemmer har udover organisationens medlemskab meldt sig direkte ind i selskabet for at støtte dets aktiviteter.

Uddannelsesinstitutionerne
Medicoindustrien har i mange år forsøgt at påvirke universitetsuddannelserne til at etablere kombinationsuddannelser, hvor de unge får mulighed for at kombinere de tekniske og medicinske kompetencer. Vi er yderst tilfredse med, at medicouddannelser har fået så høj en prioritet på såvel Aalborg universitet, Århus Universitet som DTU. Medicoindustrien er med til at præge den nye uddannelse i 'Medicin og Teknologi' via sit medlemskab af DTU's referencegruppe for uddannelsen.

Der har også i årets løb været en meget fin dialog med Danmarks Farmaceutiske Universitet (DFU). Medicoindustrien

ary. Four of the six programme modules were completed during the year, while the last two will be held in 2005. Thus the first medical device sales consultants will acquire their diplomas in June 2005. The programme is described in a separate section of this Annual Report.

Public-private sector interaction

Medicoindustrien maintains close contact with everyone who regulates, uses and sources medical devices as well as with the relevant education institutions and authorities who influence the framework conditions under which medical device companies operate.

Regulatory authorities
The secretariat staff is in frequent contact with the officers of the Medicines Agency and the National Board of Health to discuss specific cases and plan the two bodies' teaching contribution to Medicoindustrien's courses. In addition, the Board of Medicoindustrien met the executives of the Medicines Agency for an informal meeting on 16 April 2004 to discuss cases of common interest.

Users of medical devices
Medicoindustrien co-founded the Danish Patient Safety Foundation and is active on the foundation's board and executive committee. Failure of medical devices can never be totally avoided, but it should be prevented by all possible means that the same problem arises more than once. Health professionals, patients and companies all share this goal. Several members of Medicoindustrien have signed up as direct members of the foundation, in addition to our association membership, in order to support its activities.

Education institutions
For many years, Medicoindustrien has sought to encourage universities to introduce combinatory degree programmes to offer students the opportunity to combine technical and medical qualifications. We are gratified that Aalborg University, the University of Aarhus and DTU, the Technical University of Denmark, are giving high priority to medical technology programmes. Medicoindustrien is involved in defining the new 'Medicine and Technology' degree through our membership of DTU's programme reference group.

Over the past year we have also engaged successfully in dialogue with The Danish University of Pharmaceutical Sciences (DFU). The medical device industry already employs many pharmaceutical graduates and this number is not expected to lessen in future since devices will increasingly be combined with drugs.

beskæftiger allerede i dag mange farmaceuter, og det bliver ikke mindre med tiden, da mere og mere udstyr kombineres med lægemidler. Vi har derfor med DFU drøftet mulighederne for at gøre medicoindustrien mere synlig på farmaceutstudiet og for at få oprettet et særskilt medicovalgfag.

Tværfagligt samarbejde
MedicoFremtid er det netværk, der blev dannet i sommeren 2003 og som består af de fagligt stærkeste kræfter i Danmark indenfor medicoteknologi. MedicoFremtid består af deltagere fra forskningsverdenen med specielt fokus på medicoområdet, sygehusverdenen samt medicovirksomheder i Danmark - med Medicoindustrien som tovholder.

Tanken med netværket er at opnå et tværfagligt samarbejde mellem universitetsverdenen, hospitalsverdenen og medicoindustrien med det formål at øge værdiskabelsen i medicoindustrien og styrke uddannelserne og den tekniske og sundhedsvidenskabelige forskning.

Medicoindustrien søgte i sommeren 2004 på vegne af konsortiet 'MedicoFremtid' om at blive prækvalificeret til at deltage i Videnskabsministeriets udbud af højteknologiske netværk. Det lykkedes desværre ikke. Vi skal derfor i 2005 finde de fornødne ressourcer til at drive projektet andre steder.

Etiske retningslinier
Da samarbejde med sundhedspersonalet er altafgørende for medicoindustriens udvikling af nye produkter, er det vigtigt, at der ikke kan sættes spørgsmålstegn ved det. Medicoindustrien indførte derfor i 2004 et sæt etiske regler, som er blevet godt modtaget af såvel industrien som dens samarbejdspartnere.

Erhvervs- og Videnskabsministerierne
Som beskrevet i afsnittet om 'Den globale udfordring', er organisationen meget optaget af de store udfordringer medicoindustrien står overfor med udflytning af arbejdspladser og skabelse af nye i Danmark via innovation. For at opnå større indsigt i, hvad der driver innovation, og hvilke rammebetingelser virksomhedernes innovation baserer sig på, har Medicoindustrien samarbejdet med FORA og Erhvervs- og Byggestyrelsen om en undersøgelse af innovation. Vi har også sammen med Videnskabsministeriet drøftet standardiseringens rolle i relation til innovation.

Indkøberne af medicinsk udstyr
Medicoindustrien har i adskillige år haft et meget fint samarbejde med sygehusindkøberne, hvor vi forsøger at rydde sten af vejen og gøre hverdagens samhandel mere effektiv. Der afholdes blandt andet et årligt fællesseminar, som er beskrevet ovenfor i afsnittet om formidling af information. Det er via det samarbejde, at det store e-handelsprojekt blev sat i gang, ligesom samarbejdet har resulteret i fælles udbudsstandarder, som letter både udbuds- og tilbudsskrivningen.

Accordingly we have had discussions with DFU about ways to make the medical device industry more visible in their programmes and the prospect of their introducing an elective course specifically on medical devices.

Cross-sector collaboration
MedicoFuture, the network established in mid-2003, integrates the strongest professional forces in medical technology in Denmark. MedicoFuture includes partners from the research world specialising in medical technology, the hospital sector and Danish medical device companies - with Medicoindustrien at the helm.

The idea behind the network is to boost cross-sector collaboration between universities, hospitals and medical device manufacturers to underpin value creation in the industry, strengthen education programmes and promote technical and medical science research.

Representing the MedicoFuture consortium, Medicoindustrien applied for prequalification to take part in the Science Ministry's tendering process for high-tech networks in the summer of 2004 but was not successful. Thus, we need to find the resources to operate the project elsewhere in 2005.

Code of Ethics
Collaboration with healthcare professionals is vital to the industry's development of new products and thus it is vital to ensure that this collaboration cannot be questioned. In 2004 Medicoindustrien introduced a new Code of Ethics, which was well received by companies and their collaborative partners.

Interaction with the ministries of science and industry
As described under the heading 'The global challenge', our association is deeply committed to tackling the immense challenges facing the medical device industry as jobs are moved far away and new ones created in Denmark through innovation. To gain deeper insight into the drivers of innovation and the framework conditions underpinning corporate innovation, Medicoindustrien has joined forces with FORA research centre and the National Agency for Enterprise and Construction to carry out a study of innovation.In addition, we have had talks with the Ministry of Science on the role of standardisation in the context of innovation.

Purchasers of medical devices
Medicoindustrien has had excellent cooperative relations with hospital purchasers for several years, seeking to remove stumbling blocks and make ongoing trading more efficient. For example, we hold an annual joint seminar as described above under 'Communicating information'. The cooperation was also the springboard for the extensive e-commerce project, and the platform for developing common public tender standards to facilitate the drafting of both contract documents and tenders.

Kursusprogram for 2005

Forår	*Dato*
1. Softwarevalidering	1. februar
2. Introduktion til Risk Management for medicinsk udstyr	3. februar
3. Praktisk gennemførelse af risikoanalyser ved produktudvikling og produktion	1.-2. marts
4. Introduktion til kliniske afprøvninger	15. marts
5. Medicoteknisk oversættelse	29.-30. marts
6. Introduktion til medicobranchen	19.-21. april
7. Introduktion E-kataloget	maj
8. FDA's godkendelsesregler for medicinsk udstyr	10.-11. maj
9. Introduktion til Plast	18. maj
10. Reklameregler for medicinsk udstyr	1. juni
11. Design control - Quality Assurance in Product Development	6.-7. juni
12. Procesvalidering	9. juni
13. Præsentationsteknik	14.-15. juni

Efterår	*Dato*
14. Projektledelse i medicovirksomheder	august
15. Anatomi/fysiologi	29.-30. august & 26.-27. september
16. Godkendelsesregler for medicinsk udstyr i EU	september
17. Hygiejnekrav ved fremstilling af medicinsk udstyr	8. september
18. Biocompatibility	13.-14. september
19. Project Management for Clinical Trials	15.-16. september
20. How to work with CAPA - Corrective and Preventive Actions	september
21. Prækvalifikation, tilbudsgivning og EU's udbudsregler	4.-5. oktober
22. Sterilisationsprocesser	6. oktober
23. How to be an Excellent Internal Auditor in the Medical Device Industry	oktober
24. How Industry improves in Working with FDA	oktober
25. Markedsanalyser, markedsovervågning og marketing i medicoindustrien	november
26. Introduktion til medicobranchen	15.-17. november
27. Undervisningsteknik	22.-23. november

Kursusbeskrivelser og programmer for de enkelte kurser vil løbende være at finde på Medicoindustriens hjemmeside www.medicoindustrien.dk.

Såfremt der udvikles yderligere kurser i løbet af året, vil de også kunne findes på hjemmesiden.

Course Programme 2005

Spring	*Date*
1. Software Validation	1 February
2. Introduction to Risk Management for Medical Devices	3 February
3. Practical Implementation on Risk Analyses in Product Development and Manufacture	1-2 March
4. Introduction to Clinical Trials	15 March
5. Medical Device and Technology Translation	29-30 March
6. Introduction to the Medical Device Industry	19-21 April
7. Introduction to the E-catalogue	May
8. FDA Rules for Approval of Medical Devices	10-11 May
9. Introduction to Plastics	18 May
10. Rules for Medical Device Advertising	1 June
11. Design Control - Quality Assurance in Product Development	6-7 June
12. Process Validation	9 June
13. Presentational Skills	14-15 June

Autumn	*Date*
14. Project Management in Medical Device Companies	August
15. Anatomy/Physiology	29-30 August & 26-27 September
16. EU Rules for Approval of Medical Devices	September
17. Hygienic Requirements in Medical Device Manufacture	8 September
18. Biocompatibility	13-14 September
19. Project Management for Clinical Trials	15-16 September
20. How to work with CAPA - Corrective and Preventive Actions	September
21. Prequalification, Tendering and the EU Procurement Rules	4 -5 October
22. Sterilisation Processes	6 October
23. How to be an Excellent Internal Auditor in the Medical Device Industry	October
24. How Industry Improves in Working with FDA	October
25. Market Research, Post-Market Surveillance and Marketing in the Medical Device Industry	November
26. Introduction to the Medical Device Industry	15-17 November
27. Teaching and Instruction Skills	22-23 November

The course descriptions and programmes of the courses will be posted continually at Medicoindustrien's website www.medicoindustrien.dk.

If further courses are developed over the year, they will also be announced at the website.

MEDICO INDUSTRIEN

Liste over medlemmer

af Medicoindustriens udvalg og erfa-grupper

List of members

of Medicoindustrien's Standing Committees and Groups set up for Exchange of Experience

UDVALG
STANDING COMMITTEES

Udvalg om e-handel
Committee on e-Commerce

Niels Røddik,
3M A/S, Health Care
Salgs- & marketing direktør
General Sales & Marketing Manager
Formand/Chairman

Jon Bingen-Jacobsen,
Synthes A/S
Adm. direktør
Managing Director

Arne Bjerngaard
Kebo Care A/S
Logistikchef
Logistics Manager

Flemming Bundgaard
Stryker Danmark
Customer Service Manager

Finn B. Christensen
Astra Tech A/S
Økonomichef
Financial Manager

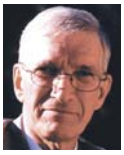
Tinna Christensen
ViCare Medical A/S
Produktchef
Product Manager

Uffe Christensen
Alcon Danmark A/S
Adm. direktør
General Manager

André Fleron
Kirudan A/S
Salgschef
Sales Manager

Sven Gammelgaard
Protesekompagniet A/S
Produktchef
Product Manager

Keld Grünfeld
K. V. Tjellesen A/S
Direktør, Leverandør Logistik
Director, Supplier Logistics



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Grøndorf Medical A/S
Administrerende direktør
Managing Director

Torben Hey
Tamro MedLab AS
Produktkoordinator
Product Coordinator

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Lohmann & Rauscher A/S
Marketing koordinator
Marketing Coordinator

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ConvaTec, BMS
Country Manager

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Markedschef
Country Manager

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Logistics Manager

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Smith & Nephew A/S
Divisionschef Medical
Medical Division Manager

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Direktør
Managing Director

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Olympus Danmark A/S
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Logistic Manager

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LJ Medical ApS
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Managing Director

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Boston Scientific Nordic AB
Tender and Pricing Specialist

Lone Pedersen
Mediplast A/S
Salgskonsulent/sygeplejerske
Sales rep./nurse

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H. Dam Kærgaard A/S
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Partner, CEO

Heinz Lorentzen
Mærsk-Andersen as
Direktør
Managing Director

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Kundeservice chef
Customer Service Manager

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Customer Service Superviser

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Sales Manager

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Biofarma Logistik A/S
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Managing Director

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General Manager

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Business Manager

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Managing Director

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Biomet Danmark ApS
Økonomidirektør
Financial Director

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Markedschef
Country Manager

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B. Braun Medical A/S
Divisionschef
Division Manager

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Direktør
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William Cook Europe ApS
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Formand/Chairman

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Direktør
Director

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Markedschef
Country Manager

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Sales & Marketing Director Nordic Countries

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Division Manager Medical

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Sales-Supervisor

Kapitalvareudvalget
Committee on Capital Goods

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Direktør
General Manager
Formand/Chairman

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Sales and Marketing Manager

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General Manager

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Santax Medico A/S
Adm. direktør
Managing director

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Direktør
Country Manager

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Produktchef
Product Manager

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Adm. direktør
Managing director

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Sectra A/S
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Agfa-Gevaert A/S
Business Manager

Udvalg om Kliniske afprøvninger
Committee on Clinical Trials

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Clinical Research, M. Sc.
Formand/Chairman

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Clinical Documentation Manager

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Clinical development manager

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Clinical Product Manager

Kvalitetssikringsudvalget
Quality Assurance Committee

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Centre Manager, B. Sc.

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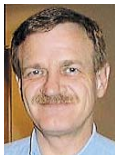
Kvalitets - og registreringschef
Director of Quality Assurance and Regulatory Affairs

Poul Ottosen
Ambu A/S
Corporate Quality Manager

Frank Petersen
Chempaq A/S
Kvalitetschef
Manager of Quality & Regulatory Affairs



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Lovgivningsudvalget
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Miljøudvalget
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Regulatory Affairs Coordinator

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Microbiologist
Formand/Chairman

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M. Sc. Chem. Engineer
Næstformand/Vice Chairman

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Pharmacist, Quality Assurance

Teknologiudvalget
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Formand/Chairman

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Centre Manager, B. Sc.

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Product Development, Manager

ERFA-grupper
Groups set up for Exchange of Experience

Erfa-gruppe for Biosikkerhed
Group set up for Exchange of Experience: Biocompatibility

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Regulatory Affairs Coordinator

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Ambu A/S
R&D Teamchef, Neurologi
R&D Team Manager, Neurology

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Toksikolog, Dyrlæge
Research Scientist, DVM

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Koncern Miljøingeniør
Corporate Environmental Engineer

Erfa-gruppe for Medicoteknisk oversættelse
Group set up for Exchange of Experience: Medical Device and Technology Translation

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Manager, Office/Translation
Formand/Chairman

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Sekretær
Secretary

Mariann Bay
Novo Nordisk A/S
Sekretær/correspondent
Bilangual Secretary

Charlotte Brahe
Coloplast A/S
Chefsekretær
Executive Secretary

Bianca M. Gravenhorst Greve
Coloplast A/S
Corporate Quality Coordinator

Kirsten Moos Johansen
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Bilangual Secretary

Inge Fabricius Madsen
Coloplast A/S
Sekretær/oversætter
Secretary/translator

Vibeke Linde Nielsen
Unomedical a/s
Korrespondent/sekretær
Trilingual Correspondent/Secretary

Valla Olafsdottir
Coloplast A/S
Chefsekretær
Executive secretary

Erfa-gruppe for Outsourcing
Group set up for Exchange of Experience: Outsourcing

Steen Ishøy
Carmo A/S
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CEO
Formand/Chairman

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Senior Production Development Manager

Palle Sick Børgesen
Kaiserplast A/S
Sales Manager, Medical Business Unit.

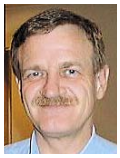
Peter Maglehøj Hansen
William Cook Europe ApS
Logistikchef
Logistic and Customer Service Manager

Preben Løvkiel
William Cook Europe ApS
Indkøbschef
Purchasing Manager

Enzo Munck
Millimed A/S
Transfer Manager

Keld Frost Nielsen
Novo Nordisk A/S
QA kvalitetskoordinator
QA Quality Coordinator

Lauritz B. Rasmussen
Coloplast A/S
Leder, Corporate Transfer Team
Corporate Transfer Team Manager



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Peter L. Saabye
Ferrosan A/S
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Udviklingschef
General Manager

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Group set up for Exchange of Experience: Process Validation

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Formand/Chairman

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FORCE Technology
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System and Management Development

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Validation Coordinator

Ulf Gottfredsen
Knudsen Plast A/S

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QA Engineer

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Process engineer

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Polytechnical Engineer

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Production Engineer

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Microbiologist, Ph.D

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Formand/Chairman

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Kvalitetsingeniør
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TriVirix Denmark ApS
Quality Engineer

Peter Werner Christensen
NNE A/S
Quality Proffesional, Computer System Compliance

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William Cook Europe ApS
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Risk Analysis Coordinator

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Chefkonsulent
Senior Consultant
Danish Technological Institute

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NM&S Site Hjørring

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Bob Olorenshaw
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Poul Skallerup
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IT Kvalitetsrådgiver
IT Quality Advisor

Erfa-gruppe for Servicechefer
Group set up for Exchange of Experience: Service Managers

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General Manager

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Santax Medico A/S
Teknisk chef
Manager Technical Department

Povl Pedersen
Philips Medico A/S
Servicechef
Service Manager

Henrik Petersen
Afga-Gevaert A/S
Servicechef
Services Manager

Per Overgaard Rasmussen
ViCare Medical A/S
Servicechef
Service Manager

Erik Schilling
N.C. Nielsen Hospitalsudstyr A/S
Servicechef
Technical Service Manager

Ole Theilgaard
KIVEX A/S
Servicechef
Service Manager

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Group set up for Exchange of Experience: Software Validation

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Formand/Chairman

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Project Manager

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Installations Manager

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QA & Laboratory Manager

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Validation Coordinator

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Chempaq A/S
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Validation Supervisor

Dorte Bjørn Reland
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Quality Coordinator
Novo Nordisk A/S

Poul Skallerup
Novo Nordisk A/S
IT Kvalitetsrådgiver
IT Quality Advisor

Medicoindustrien's Meeting Calendar 2004

Date	*Event*
January	
5.	Steering Committee for the Medical Device Consultants' Programme, meeting
6.	Medicoindustrien's Committee on Capital Goods, meeting
7.	Medicoindustrien's meeting with Aarhus Community Hospital and Aarhus Region
7.	Medicoindustrien's meeting with the Science Park at Skejby Hospital
8.	Medicoindustrien's Experience Group on Process Validation, meeting
9.	Introductory meeting for the Medical Device Consultants' Training Programme
12.	Medicoindustrien's Experience Group on Outsourcing, meeting
13.	Medicoindustrien's Experience Group for Service Managers, meeting
14.	Medicoindustrien's meeting with the Danish Society for Medical Technology at Odense University Hospital
15.	Medicoindustrien's members meeting about Lifecycle Analysis and Future Problem Substances
19.	Medicoindustrien's Committee on Medical Disposables, meeting
20.	Medicoindustrien's Environmental Committee, meeting
20.	EUCOMED Association Secretaries Council, meeting
28.	Meeting of the Steering Committee for the E-commerce Project between the Danish Regions and Medicoindustrien
29.	Medicoindustrien's Legal & Regulatory Affairs Committee, meeting
29. – 30.	Medical Device Sales Consultants' Programme, Module 1: Anatomy and Physiology, 1st session
February	
3.	Medicoindustrien's Course on Software Validation
4.	Medicoindustrien's Experience Group on Clean Rooms and Microbiological Test Methods
4.	Medicoindustrien's Sterilisation Committee, meeting
5.	Medicoindustrien's Board, meeting
10.	Website Group of the MedicoFuture Workshop Group, meeting
12.	MedicoFuture Workshop Group, meeting
17.	Medicoindustrien's Technology Committee, meeting
18.	Meeting of the Steering Committee for the E-commerce Project between the Danish Regions and Medicoindustrien
20.	Medicoindustrien's Hearing on Reusing Single-use Devices
23.	Meeting with FORA, the centre for business economic research and analysis under the Danish Ministry of Economic and Business Affairs
24.	Medicoindustrien's Committee on Clinical Trials and Biocompatibility, meeting
25.	Medicoindustrien's Course on Hygiene Requirements in the Manufacture of Medical Devices
25.	Meeting with the Board of the Danish Society for Biomedical Technology
26.	EUCOMED Regulatory Focus Group, meeting

Date	*Event*
March	
1.	Medicoindustrien's Quality Assurance Committee, meeting
3. – 4.	Medicoindustrien's Course on Risk Management
4.	Medicoindustrien's Committee on Medical Disposables, meeting
8. – 9.	Medical Device Sales Consultants' Programme, Module 1: Anatomy and Physiology, 2nd session
11.	Steering Group for Co-operation between Regional Purchasers & Medicoindustrien, Meeting
11.	Board Meeting of the Danish Patient Safety Foundation
12.	Steering Group for the E-commerce Project between the Danish Regions and Medicoindustrien, meeting
17. – 18.	Medicoindustrien's Course on Medical Device and Technology Translation
23.	Medicoindustrien's Environmental Committee, meeting
24.	The Centre Council for the Danish Centre for Evaluation and Health Technology Assessment, meeting
25.	Medicoindustrien's Board, meeting
25.	Medicoindustrien's Annual General Assembly
25.	Medicoindustrien's Experience Group on Process Validation, meeting
30.	Medicoindustrien's Committee on Capital Goods, meeting
30. March – 1. April	Medicoindustrien's Course on Introduction to the Medical Device Industry
31.	Medicoindustrien's Committee on E-commerce, meeting
April	
6. – 7.	Notified Bodies meeting
13.	Medicoindustrien's Technology Committee, meeting
14.	Medicoindustrien's Experience Group on Outsourcing, meeting
15.	Danish Patient Safety Foundation, Annual General Meeting
16.	Meeting with the Chief Executive of the Danish Medicines Agency
20.	Medicoindustrien's Experience Group on Clean Room and Microbiological Test Methods
20.	Medicoindustrien's Sterilisation Committee, meeting
22. – 23.	Joint Regional Purchasers/ Medicoindustrien Seminar
23.	Medical Device Sales Consultants' Programme, Module 1: Anatomy and Physiology – Exam
27.	Medicoindustrien's Experience Group on Risk Management, meeting
29.	Medicoindustrien's Legal & Regulatory Affairs Committee, meeting
May	
3.	Medicoindustrien's Quality Assurance Committee, meeting
4.	Medicoindustrien's Experience Group for Service Managers, meeting

Date	*Event*
4.	Medicoindustrien's Experience Group on Software Validation, meeting
5.	Meeting of the Steering Committee for the E-commerce Project between the Danish Regions and Medicoindustrien
10.	Medicoindustrien's course on Process Validation
10.	Website Group of the MedicoFuture Workshop Group, meeting
13. – 14.	Medical Device Sales Consultants' Programme, Module 2: Disease Knowledge, 1st session
18.	Medicoindustrien's Committee on Medical Disposables, meeting
19.	Steering Group for Co-operation between Regional Purchasers & Medicoindustrien, Meeting
24.	Start-up Meeting of the Experience Group on Medical Device and Technology Translation
26.	The Steering Committee for the Medical Device Sales Consultants' Programme, meeting
27.	Medicoindustrien's Board, meeting
27.	Medicoindustrien's Course on Advertising Rules for Medical Devices
June	
1.	EUCOMED Association Secretaries College, meeting
3.	Meeting between Medicoindustrien and the Working Group for Medical Technology Managers
3.	Medicoindustrien's Experience Group on Process Validation, meeting
10.	Medicoindustrien's Environmental Committee, meeting
11.	Medical Device Sales Consultants' Programme, Module 2: Disease Knowledge, 2nd session
14.	Medicoindustrien's Experience Group on Clean Rooms and Microbiological Test Methods
14.	Medicoindustrien's Sterilisation Committee, meeting
15.	Medicoindustrien's Committee on Capital Goods, meeting
16.	EUCOMED Regulatory Focus Group, meeting
17.	Medicoindustrien's Technology Committee, meeting
17.	Medicoindustrien's Legal & Regulatory Affairs Committee, meeting
21.	Meeting of the Steering Committee for the E-commerce Project between the Danish Regions and Medicoindustrien
21.	Medical Device Sales Consultants' Programme, Module 2: Disease Knowledge – Exam
24. – 25.	Medicoindustrien's Course on Biocompatibility Testing & Management
28.	Medicoindustrien's Committee on Clinical Trials and Biocompatibility, meeting
July	
2.	Steering Group for Co-operation between Regional Purchasers & Medicoindustrien, Meeting
August	
12.	Medicoindustrien's Experience Group on Medical Device and Technology Translation
17.	Medicoindustrien's Experience Group on Software Validation, meeting
19.	Medicoindustrien's Members' Meeting about setting up activities in China

Date	*Event*
19.	Medicoindustrien's Experience Group on Risk Management, meeting
24.	Medicoindustrien's Committee on Medical Disposables, meeting
30.	Medicoindustrien's Committee on Quality Assurance, meeting
30. – 31.	Medicoindustrien's Course on Human Anatomy and Physiology, part 1
September	
1.	Set-up meeting of Medicoindustrien's Experience Group on Biocompatibility
1.	Set-up meeting of Medicoindustrien's Committee on Clinical Trials
1.	Medicoindustrien's Sterilisation Committee, meeting
2.	Medicoindustrien's Environmental Committee, meeting
3.	Medicoindustrien's Committee on E-commerce, meeting
7.	Medicoindustrien's Committee on Capital Goods, meeting
8.	Medicoindustrien's Experience Group on Clean Rooms and Microbiological Test Methods
8. – 9.	Medicoindustrien's Board, meeting and Strategy Seminar
9.	Medicoindustrien's members' meeting on Packaging and Electronic Waste
13.	Medicoindustrien's Course on the EU Approval Rules for Medical Devices
14.	Medicoindustrien's Technology Committee, meeting
14.	Medicoindustrien's Committee on Clinical Trials and Biocompatibility, meeting
21.	Medicoindustrien's Experience Group for Service Managers
24.	Medical Device Sales Consultants' Programme, Module 3: Structure of the Danish Healthcare System
27. – 28.	Medicoindustrien's Course on Quality Assurance in Product Development
29.	Medicoindustrien's Legal & Regulatory Affairs Committee, meeting
29.	Medicoindustrien's Experience Group on Biocompatibility, meeting
30.	Medicoindustrien's Course on Process Validation
30.	Medicoindustrien's Experience Group on Process Validation, meeting
October	
4. - 5.	Medicoindustrien's Course on Human Anatomy and Physiology, part 2
5.	Medicoindustrien's Experience Group on Software Validation, meeting
5.	Meeting of the Steering Committee for the E-commerce Project between the Danish Regions and Medicoindustrien
6.	EUCOMED Association Secretaries Council, meeting
7. – 8.	EUCOMED Annual General Meeting
14.	EUCOMED Regulatory Focus Group, meeting
19.	Medicoindustrien's Course on Prequalification and Drafting Tenders
27.	Medicoindustrien's Committee on Medical Disposables, meeting

Date	*Event*
28.	Medicoindustrien's Board, meeting
29.	Medical Device Sales Consultants' Programme, Module 3: Structure of the Danish Healthcare System - Exam
November	
1.	Medicoindustrien's Committee on Quality Assurance, meeting
2.	The Executive Committee of the Danish Patient Safety Foundation, meeting
4.	The Council of Medical Museion, meeting
5.	Meeting of the Steering Committee for the E-commerce Project between the Danish Regions and Medicoindustrien
9.	Medicoindustrien's Technology Committee, meeting
9. – 11.	Medicoindustrien's Course on Introduction to the Medical Device Industry
12.	Medicoindustrien's members meeting on E-invoices and Interaction with the Medical Device Project
16.	Medicoindustrien's Committee on Capital Goods, meeting
17.	Medicoindustrien's Course on the New EU Procurement Rules
17.	Meeting about the Innovation Centre for Medical Technology
17. – 18.	Medicoindustrien's Course on Introduction to AMKAT, the Regions' e-commerce catalogue
18.	Medicoindustrien's Experience Group on Medical Device and Technology Translation
19.	Medicoindustrien's Course on Critical Literature Evaluation
23.	Medicoindustrien's Experience Group on Clean Rooms and Microbiological Test Methods
25.	Medicoindustrien's Legal & Regulatory Affairs Committee, meeting
25.	Medicoindustrien's Experience Group on Process Validation, meeting
29.	Danish Patient Safety Foundation, Board Seminar
30.	Medicoindustrien's Committee on Medical Disposables, meeting
30.	EUCOMED Association Secretaries Council Task Force Meeting
30. November – 1. December	Medicoindustrien's Course on Instruction Techniques
December	
1.	Steering Group for Co-operation between Regional Purchasers & Medicoindustrien, Meeting
2.	Medicoindustrien's Sterilisation Committee, meeting
8.	Meeting with the Ministry of Science, Technology and Innovation regarding E-commerce
10.	Medical Device Sales Consultants' Programme, Module 4: Regulations for Approval of Medical Devices
10.	Medicoindustrien's Technology Committee, extraordinary meeting
14.	Medicoindustrien's Experience Group on Outsourcing, meeting
14.	Medicoindustrien's Committee on Clinical Trials, meeting
15.	Meeting of the Steering Committee for the E-Commerce Project between the Danish Regions and Medicoindustrien

Date	*Event*
16.	Medicoindustrien's Board, meeting
16.	Steering Committee for the Medical Device Consultants' Programme, meeting
20.	Medicoindustrien's Committee on Quality Assurance, meeting
21.	Medicoindustrien's Environmental Committee, meeting

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