BJ Media

The Leading Life Science Magazine in Scandinavia

Dec. / Jan. 13-14

Medicon Valley

Nordic Life Science

Annual Review 13-14

ISPE marks 10-year anniversary

Announces new gala celebration during the society's 2014 pharmaceutical quality week as the awards program enters its second decade

After 10 years of setting the standard, ISPE announced that it has made significant enhancements to its annual Facility of the Year Awards (FOYA) program, the premier global awards program focused on recognizing the innovation and creativity in manufacturing facilities serving the regulated healthcare industry. These enhancements are designed to celebrate the tenth anniversary of this distinguished awards program and include a new gala to recognize Category Winners at the annual ISPE-FDA CGMP Conference (part of ISPE's newly created Pharmaceutical Quality Week) and an expanded presence for Category Winners at the ISPE Annual Meeting.

The quest for excellence

- Over the past decade, the pharmaceutical and biopharmaceutical industry has made significant advancements in the technology and processes used in building and renovating manufacturing facilities, said Nancy Berg, ISPE President and CEO.
- These advancements reflect the industry's quest for excellence and superior product quality. As the premier awards program focused on recognizing these achievements, it is only fitting that the Facility of the Year Awards also make advancements in the way it showcases the Category Winners' momentous accomplishments. By bringing the annual celebratory events for FOYA to Pharmaceutical Quality Week and the ISPE Annual Meeting, ISPE will present these innovative facilities to a global audience of top pharmaceutical leaders and regulators.

The 2014 awards program is now accepting entries through 3 February 2014. Category Award Winners will be recognized in June in six categories: Operational Excellence, Project Execution, Equipment Innovation, Process Innovation, Sustainability, and Facility Integration. Companies interested in submitting their newly constructed or renovated facilities for the 2014 FOYA program can find complete eligibility criteria, program timelines and required entry forms at www.FacilityoftheYear.org/SubmitYourFacility.

Facility of the Year Awards Program

Sponsored by ISPE, the Facility of the Year Awards (FOYA) is an annual program recognizing state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies to enhance the delivery of a superior project, as well as reduce the cost of producing high-quality medicines.

Join forces to further enhance diabetes research

Oxford University and Novo Nordisk has announced the establishment of an international fellowship programme that aims to support the career and scientific development of young, exceptional research talent within diabetes

The partnership will establish a number of postdoctoral fellowship opportunities that will be hosted by Oxford University and funded by Novo Nordisk.

- We are honoured to establish the International PostDoctoral Fellowship Programme with Oxford University, which has such valuable expertise in the study and treatment of diabetes. By combining our company's discovery and clinical development strengths with the research expertise and academic tradition of Oxford University, we can support the development of a new generation of exceptional diabetes researchers to eventually drive innovation further and improve the lives of the patients, said Mads Krogsgaard Thomsen, executive vice president and chief science officer at Novo Nordisk.

A new generation of research leaders

As part of the agreement, a total of 12 young leading researchers will be offered a 3-year grant to support their research within the fields of diabetes, metabolism and endocrinology. The goal of the new programme is to support the development of a new generation of research leaders while further developing scientific excellence within diabetes.

- This new programme will support the best young researchers doing novel work in the understanding of diabetes and its treatment. It is these early career researchers that will produce the new ideas, discoveries and advances that will improve diabetes treatment and care in the future. We're delighted to partner with Novo Nordisk to provide this level of funding and support which will be important in enabling both their research and their career development, said Professor Hugh Watkins of the Radcliffe Department of Medicine at Oxford University.

A joint steering committee with members from both Oxford University and Novo Nordisk will oversee the programme and assess research proposals from scientists at both organisations. The first four fellows in the programme will start in the autumn of 2014.

New ambitious center delves into protein drugs of the future

Designing new drugs based on the body's own molecules will be the focus of a new Center for Biopharmaceuticals that was launched at the Faculty of Health and Medical Sciences on 1 November. The Center will help solve the pharmaceutical challenges of the future in the field of biological drugs

The Center for Biopharmaceuticals will be a pioneering force in technologies that combine the principles and tools of chemistry with the synthetic strategies and processes of living organisms to create proteins with completely novel properties. The Center will build on the strong multi-disciplinary relationship between the Faculty of Health and Medical Sciences' two pharmaceutical departments, the Department of Drug Design and Pharmacology and the Department of Pharmacy.

Protein drugs are based on nature's own design. That's a big plus, because it means they are in tune with the body's own raw material. It means drugs with less severe side-effects. Currently more than half of drugs that are being tested in clinical trials are so-called biopharmaceuticals – consisting of proteins, peptides of nucleic acids – and the number is rising steadily.

- The ability to manipulate proteins, known as protein engineering, has paved the way for important breakthroughs in biotechnology and biomedicine. Proteins can for instance target certain cell processes with very high precision – and drugs based on proteins or peptides enable new ways to treat many diseases, says Ole Thastrup, Professor and Head of the Department of Drug Design and Pharmacology, Faculty of Health and Medical Sciences.

Pioneering research in chemical biology

The Center for Biopharmaceuticals is an ambitious "beacon" at the forefront of pharmaceutical protein and peptide research. Proteins play a fundamental role in biological processes. They consist of strings of amino acids – so-called peptides – composed of up to 20 different amino acids. The composition, structure and function of proteins are controlled by the genetic code. At the new Center for Biopharmaceuticals, bright minds from around the world will be looking into rewriting this universal code:

- To bring about the next major leap forward in protein science, we need to break through one of the greatest barriers of conventional protein engineering – the ability to 'write' protein recipes using other 'letters' than those 20 that make up the genetic alphabet, says Professor Kristian Strømgaard, who has been appointed Director of the new Center for Biopharmaceuticals.

Features

Researchers identify main genes responsible for asthma attacks in children

By Louise Graa Christensen

An international team spearheaded by researchers from the University of Copenhagen has identified the genes that put some children at particularly high risk of serious asthma attacks, including one not previously suspected of being implicated in the disease. In the long term, these new findings are expected to help improve treatment options for the disease, which represents a high cost for families and society alike

Asthma is the most frequent chronic disease in children and also the most common reason for Danish children being admitted to hospital. Very young children are at especially high risk of severe asthma attacks requiring hospitalisation. This is hard on both child and family and severely strains society's resources.
Nonetheless, doctors still have insufficient knowledge about asthma attacks in infants, making the condition difficult to prevent and treat. It is hoped that the recent research findings will help change this. An international team spearheaded by researchers from the Faculty of Health and Medical Sciences have now identified the genes that put some children at risk of experiencing severe asthma attacks. The results have been published in the prestigious scientific journal Nature Genetics.
- Our results show that asthma attacks requiring young children to be hospitalised are usually genetically related. Genes play a far greater role in children with asthma than in adults. By screening children's DNA we've discovered that a gene called CDHR3, which was previously unassociated with the disease, plays a key role for the development of asthma, particularly in the very early years of life. Our study supports the theory that asthma is not just a single disease, but a complex of several sub-types that should be genetically mapped and understood individually if we are to prevent and treat the disease properly in future, says Klaus Bønnelykke, MD, PhD. He works for the Copenhagen Studies of Asthma in Childhood (COPSAC), the Danish Pediatric Asthma Center, Copenhagen University Hospital.
The researchers have studied the genes of 1,200 young children aged between two and six who had been hospitalised several times because of severe asthma attacks, and compared them with 2,500 healthy people.

Individualised treatment

Today doctors use the same medication to treat different types and degrees of asthma, but the researchers hope that improved understanding of the sub-types of the disease will pave the way for individualised treatment in future.
- Although good asthma medication is available today, it doesn't work for everyone. Specifically we need effective medicine to prevent very young children from being hospitalised and to treat them once they have been admitted. That's why we started looking at this particular group. Because asthma symptoms are fairly similar in all children, doctors tend to approach the condition in the same way. However, in reality asthma has many different underlying mechanisms, which need to be individually mapped, says Klaus Bønnelykke.
He explains that to date researchers have focused on various theories about asthma attack prevention in young children, for example, recommending breastfeeding and avoiding pets and dust mites in the home.
- We know that children exposed to smoking have a higher risk of asthma attacks, but beyond that, none of our advice has really helped, and we won't make any progress until we understand the individual sub-types of asthma and their underlying mechanisms. In this respect knowledge about risk genes is an important step in the right direction, he points out.

Asthma is the most frequent chronic disease in children

Large volume of data

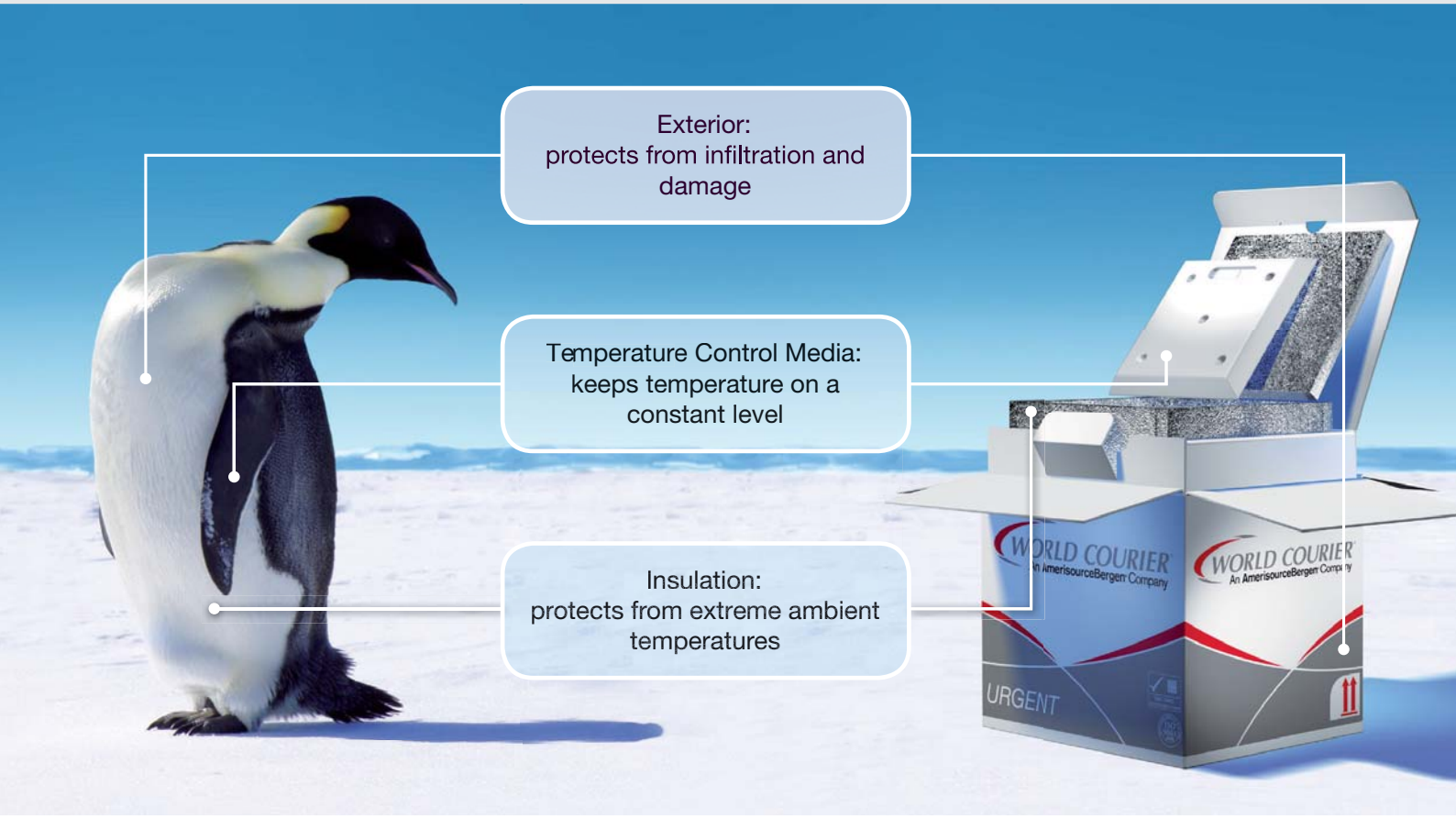
The study was headed by Klaus Bønnelykke and his colleague Hans Bisgaard, Professor of Paediatrics at the University of Copenhagen, chief physician of the Copenhagen Studies of Asthma in Childhood (COPSAC) and head of the Danish Paediatric Asthma Center. The study was conducted in collaboration with various research groups, including the Danish Centre for Neonatal Screening, Statens Serum Institut, Copenhagen, and Center for Biological Sequence Analysis (CBS), Technical University of Denmark as well as research teams in the USA, Spain, the UK and the Netherlands.
The study was based on examinations of 1,200 Danish children hospitalised for asthma and 2,500 healthy individuals. Two- to six-year-old children who had been hospitalised at least twice were identified in the hospital records. Their DNA was then screened for risk genes, and subsequent studies of children from Denmark and abroad confirmed the discovery of a new risk gene (CDHR3).

the CDHR3 gene

CDHR3 impacts the lungs directly, and the new research results indicate that it plays a particularly important role in the lungs of young children with severe asthma.
Over time the researchers hope to be able to map the precise mechanisms involving the gene as well as the environmental factors that trigger activation of the gene in some children. The goal is to be able to prevent and treat the disease with customised medication.

Publishing company: BJ Media, Tingaardsvej 4 - Valore, DK-4130 Viby Sj, Denmark
Phone: +45 8230 7500
E-mail: info@medicon-valley.dk
Web: www.medicon-valley.dk
Editor: Knud Meldgaard, editor-in-chief
Journalists: Viggo Mortensen, Sussie Munk and Chris Tachibana
Production coordinator: Simon Busk Vestergaard
Layout and reproduction: SvendborgTryk
Cover photo: Messe Duesseldorf
Printing: SvendborgTryk A/S
Distribution: PostDanmark
ISSN: 1603-4880

Experts in Temperature Control



The new GTC packaging system:

- is qualified to ISTA standards and available in sizes ranging from 4 to 96 liters of product capacity and for product temperatures of: +2°C to +8°C | +15°C to +25°C | -15°C to -25°C
- utilizes vacuum-insulated panels and specific phase change material gel-packs for superior performance over extended periods of time
- accommodates an increased payload, generally lowering freight costs and resulting in overall cost reductions
- is a multi-use system significantly reducing our environmental footprint

For further information, contact your local World Courier office.

WORLD COURIER
An AmerisourceBergen Company

COPENHAGEN: +45 32 46 06 80 | HELSINKI: +358 9 8700 3300 | OSLO: +47 63 94 62 00 | STOCKHOLM: +46 8 594 414 80

Positive response to redesign of the conference programme

Edited by editor-in-chief Knud Meldgaard

MEDICA and COMPAMED 2013 keeping pace with the market: increased emphasis on internationality

Good international business contacts are becoming increasingly important for manufacturers of medical technology and medical products. Only those that are well-positioned at the international level are able to balance weaknesses in individual markets and profit in the long run from a market that, seen globally, is growing. That is the key message conveyed after four days of events (20-23 November 2013) at MEDICA 2013, the world's largest medical trade fair, and COMPAMED 2013 (20–22 November 2013), the leading trade fair for the supplier market for medical technology manufacturing. More than half of the some 132,000 trade visitors (2012: 130,600) came from abroad, arriving from more than 120 countries. From the 4,641 exhibitors representing 66 countries, visitors obtained information on the entire spectrum of new products for high-quality, efficient medical care – ranging from medical technology and electromedicine, laboratory technology, physiotherapy products and orthopaedic technology to health IT.

MEDICA is the leading platform

- We have observed a growing number of visitors in recent years particularly from those emerging countries that are especially promising for the medical technology industry, namely from among Asian countries, from India, Russia as well as South America and China, stated Joachim Schäfer, managing director of the Messe Düsseldorf, which has solidly positioned MEDICA as a leading platform for the global "MedTech" business, with an unrivalled level of internationality. This assessment is shared by Germany's leading industry associations: SPECTARIS, ZVEI and BVMed draw attention to the significance of exports in their current market forecasts on MEDICA 2013. According to these reports, international business in the meantime accounts for 68 percent of the almost 23 billion euros in current annual revenues generated by medical technology in Germany.

- Not only is the export quota high. Foreign trade is almost the only factor driving growth. "On the other hand, competition in the German market is tough, not least because of the many international players, Tobias Weiler, managing director of SPECTARIS, explained. The German Medical Technology Association (BVMed) sees purchasing pools as the reason for increasing pressure on prices in Germany. Such concentration of purchasing power is a further market trend reflected at MEDICA.

- The number of entities maintaining hospitals is decreasing. Demand is thus becoming concentrated in increasingly larger medical care networks and hospital groups. Consequently, especially high-level decision-makers are attending MEDICA, noted Horst Giesen, director of MEDICA + COMPAMED with Messe Düsseldorf, underscoring the senior decision-making powers of visitors to MEDICA. More than 80 percent play a major role or provide expert advice in purchasing decisions.

Practical know-how and specialised knowledge

To accommodate, through both trade fair and conference events, the continually growing number of international visitors seen in recent years, the previous conference programme was completely revised for MEDICA 2013. The newly planned MEDICA EDUCATION CONFERENCE was well attended on every day of the event. The conference included, on the one hand as a necessary basis, courses providing advanced training on topics for general practitioners and practical training on devices, which afforded national and European CME certification, as well as high-level scientific workshops on focus topics, presented by highly prominent speakers. These presentations, which were held bilingually (i.e. in German and English), featured current aspects relating to gender medicine, infectiology, hygiene and personalised medicine. Among the speakers was Professor Sir John Burn of Newcastle University, one of the world's most highly regarded experts in human genetics.

As has been planned for some time, from 2014 on, the German Society for Internal Medicine (DGIM) will serve as a partner for organizing professional aspects of the MEDICA EDUCATION CONFERENCE. With more than 22,000 members, the DGIM is one of the largest professional medical associations in Europe. Commenting on the prospects, conference president Professor Hendrik Lehnert stated:

- High-profile speakers from Germany and other countries will present information on innovations in science and technology with relevance for the international community, in this way making the conference a driver of advances at hospitals, in practice and in the industry.

Other offerings at this year's event that were aimed at an international audience, and thus held in English, were the International Conference on Disaster and Military Medicine – DiMiMED, and the MEDICA MEDICINE + SPORTS CONFERENCE, addressing special concerns of sports medicine. As premiers at this year's event, both conferences were extremely well attended and succeeded in closely knitting a transfer of medical knowledge on the one hand with presentations, by MEDICA exhibitors, of related product innovations on the other. Such products include wearable applications for recording vital body data, "anti-gravity" treadmills that support gentle rehab training and, of particular interest for disaster and military medicine, mobile medical imaging systems as well as emergency equipment for on-site first aid.

Hospital Conference

The challenges facing hospital policy were the focus of the 36th German Hospital Conference, held under the general theme of Fair Funding – Hospitals in Need of a Future. In addition to the policy discussion, featured topics included the challenges to nursing care management raised by an ageing population, hospital planning and outpatient specialist care. It was gratifying to see the interest shown in the European Hospital Conference, which took place as part of the event for the second time. Among the topics discussed by the international visitors to the conference was the implementation of patient rights in the context of cross-border health care. Also well attended were the German Hospital Federation's information event on further development of the case-based remuneration system and on the new fee system for psychiatric and psychosomatic institutions. Almost 1,900 visitors attended the German Hospital Conference and the European Hospital Conference.

Movement in the IT market

The innovations presented by MEDICA exhibitors clearly point to the fact that IT is increasingly penetrating the entire health care sector, including the patient sector. Examples include a great number of wireless solutions for real-time patient monitoring as well as compact telemedicine applications designed to be used at great distances from doctors' offices and clinics. The choice of compact, easy-to-use devices for measuring various body parameters is growing rapidly. Data analysis for such devices is provided by matching health apps that run on smartphones or tablet PCs.
Yet, the more sensitive the data transferred, the more pressing the issue of data privacy. Relevant responses to the question were given at the MEDICA HEALTH IT FORUM in hall 15. "Big data" was one of the key current discussion topics. It became clear that physicians and patients for the most part probably feel safe about their data, at least when handled by the telematics infrastructure used for the electronic health card (eGK). In this case patient data are stored at the location where they were kept previously, as printed files – at the doctor's office.
Much attention was paid to the presentation of a hospital information system (HIS) equipped with newly designed features. Under the label of "United Web Solutions", several companies offering specialised software have joined forces to develop a modern, web-based and cloud-ready system. Solutions such as this one might be capable of shaking up Germany's HIS market, which has been described as "seized up".
Another striking feature of the MEDICA 2013 was the large number of medical imaging innovations, particularly in the area of ultrasonics. From a low-priced entry-level device with premium features from the next higher class, to a high-end system for complex applications as an alternative to CT or MRI screening – purchasing managers were able to choose from any ever broader selection of devices.

COMPAMED

COMPAMED, the international trade fair for the supplier market for medical technology manufacturing, was held parallel to MEDICA. With 681 exhibitors from 37 countries, a new historical record was set for the event. The exhibitors presented to the some 17,000 visitors an abundance of technology and service solutions for use in the "MedTech" industry – everything from new materials, components, preliminary products, packaging and services to complex micro system and nanotechnology. The undeniable trend among the displayed products: enormous advances can be packed into the most highly miniaturised components. Examples of this include micro-components and modules for tools used in minimally invasive surgery.
Date of the next MEDICA Düsseldorf: 12-15 November 2014 / Date of the next COMPAMED in Düsseldorf: 12-14 November 2014.
For more information visit the websites: www.medica.de and www.compamed.de.

Do you want to stay informed?

Medicon Valley Magazine - the leading life science magazine in Scandinavia covering news on science, economics, R&D, jobs and people from the Life Science and the Biotech Industries – is brought as e-magazine directly in your mailbox.
Can you live without it…

Please send mail to: *info@medicon-valley.dk - for a free subscription.*

This is a free service from Medicon Valley Magazine, where you receive a link to the online publication, so the magazine do not take up space in your mailsystem, and you can browse it as a life-size magazine.

More information: Ph. +45 8230 7500 • info@medicon-valley.dk • www.medicon-valley.dk

Proteins suppress useless gene activity in human cells

By Peter Refsing Andersen, Torben Heick Jensen & Lisbeth Heilesen

From left: Torben Heick Jensen, Michal Domanski and Peter Refsing Andersen (Photo: Lisbeth Heilesen)

A new study shows how our cells sort the wheat from the chaff in a tangle of useful and useless gene molecules

In collaboration with international research groups, a Danish research team from Aarhus University has now found a mechanism that helps the cells prevent accumulation of the many useless RNA molecules being constantly produced by runaway gene activity in our cells. These findings contribute to a new understanding of our genes and may eventually help our understanding of gene activity in stem cells and cancer.

Protein is made from template molecules called RNA molecules, which are copies of segments of our DNA strands – our genes. A few years ago, a research team from Aarhus University showed that the generation of RNA is far more chaotic than previously assumed. In fact, most of the RNA molecules produced in our cells do not contain any information that is useful in protein synthesis. The accumulation of these molecules is therefore potentially damaging to our cells. In collaboration with international research groups, the same research team has now found a mechanism that helps our cells remove the many useless RNA molecules produced.

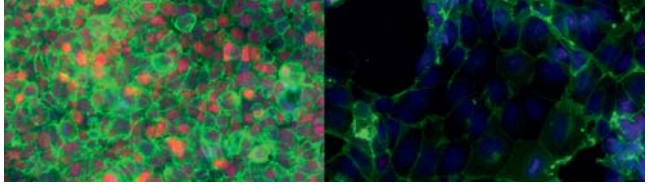
Contributes to future insight

The scientists have found proteins that recognise the 'runaway gene activity' that produces the useless RNA molecules. Runaway gene activity arises when the production of RNA runs in the wrong direction on the DNA strands or when a stop signal in the DNA is overlooked and the synthesis therefore runs too far. When the proteins recognise runaway gene activity, they derail the process and channel the useless RNA molecules into a degradation process. In this way, the cells manage to both suppress the production and degrade the product using just one mechanism.

The detected proteins have previously been associated with stem cell development and cancer. An understanding of how these proteins actually function inside the cell is therefore an important prerequisite for finding their possible roles in disease. The new findings may therefore contribute to future insight in this regard.

The work was carried out by Postdoctoral Fellows Peter Refsing Andersen and Michal Domanski and other members of the Torben Heick Jensen laboratory at the Danish National Research Foundation's Centre for mRNP Biogenesis and Metabolism, Department of Molecular Biology and Genetics, Aarhus University. The work was done in collaboration with research groups from Odense, Montpellier, Stockholm, Dresden and New York. The new results have just been published online in the journal Nature Structural & Molecular Biology.

The research group is also co-author of another article on the same subject, also published online in Nature Structural & Molecular Biology.



Embryonic stem cells stick together (green, left image) while they express Oct4 protein in their nuclei (magenta, left). When Oct4 is removed their shape changes and their adhesion to each other is reduced (right panel, nuclei in blue)

Why stem cells need to stick with their friends

By Eleanor Cowie

Scientists at University of Copenhagen and University of Edinburgh have identified a core set of functionally relevant factors which regulates embryonic stem cells' ability for self-renewal. A key aspect is the protein Oct4 and how it makes stem cells stick together. The identification of these factors will be an important tool in devising better and safer ways of making specialised cells for future regenerative cell therapies for treatment of diseases like diabetes and Parkinson's disease. The results have been published in the scientific journal Current Biology

Scientists have known that the protein Oct4 plays a key role in maintaining the embryonic stem cells in pure form by turning on stem cell genes, however up until now it has not been know which of the 8.000 or more possible genes that Oct4 can choose from actually support self-renewal. By comparing the evolution of stem cells in frogs, mice and humans, scientists at the Danish Stem Cell Center (DanStem) and The MRC Centre for Regenerative Medicine in Edinburgh have now been able to link the protein Oct4 with the ability of cells to stick together. They found that for embryonic stem cells to thrive they need to stick together and Oct4's role is to make sure they stay that way.

- Embryonic stem cells can stay forever young unless they become grown-up cells with a specialised job in a process called differentiation. Our study shows that Oct4 prevents this process by pushing stem cells to stick to each other, says Dr Alessandra Livigni, Research Fellow at the University of Edinburgh.

Identification of specific genes

The research teams in Edinburgh and Copenhagen successfully identified 53 genes, out of more than 8.000 possible candidates that together with Oct4, functionally regulate cell adhesion. Almost like finding needles in a haystack the scientists have paved the way for a more efficient way of maintaining stem cells as stem cells.

- Embryonic stem cells are characterized, among other things, by their ability to perpetuate themselves indefinitely and differentiate into all the cell types in the body – a trait called pluripotency. Though to be able to use them medically, we need to be able to maintain them as stem cells, until they're needed. When we want to turn a stem cell into a specific cell for example; an insulin producing beta cell, or a nerve cell like those in the brain, we'd like this process to occur accurately and efficiently. We cannot do this if we don't understand how to maintain stem cells as stem cells, says Professor Joshua Brickman from DanStem, University of Copenhagen.

Future potential

As well as maintaining embryonic stem cells in their pure state more effectively, this new insight will also enable scientists to more efficiently manipulate adult cells to revert to a stem cell like stage known as induced pluripotent stem cells (iPS cells). These cells have many of the same traits and characteristics as embryonic stem cells but can be derived from the patients to both help study degenerative disease and eventually treat them.

- This research knowledge has the potential for us to change the way we grow stem cells, enabling us to use them in a less costly and more efficient way. It will help us devise better and safer ways to create specialised cells for future regenerative medicine therapies, concludes Professor Joshua Brickman.

Read the scientific article in Current Biology: www.cell.com/current-biology/abstract/S0960-9822(13)01195-0

Study shows therapeutic potential of fat-derived stem cells declines as donor's age rises

By Sharon Lee

A new study released in STEM CELLS Translational Medicine demonstrates that the therapeutic value of stem cells collected from fat declines when the cells come from older patients

- This could restrict the effectiveness of autologous cell therapy using fat, or adipose-derived mesenchymal stromal cells (ADSCs), and require that we test cell material before use and develop ways to pretreat ADSCs from aged patients to enhance their therapeutic potential, said Anastasia Efimenko, M.D., Ph.D. She and Nina Dzhoyashvili, M.D., were first authors of the study led by Yelena Parfyonova, M.D., D.Sc., at Lomonosov Moscow State University, Moscow.

Cardiovascular disease remains the most common cause of death in most countries. Mesenchymal stromal cells (MSCs), stem cells collected from either bone marrow or adipose tissue, are considered one of the most promising therapeutic agents for regenerating damaged tissue because of their proliferation potential and ability to be coaxed into different cell types. Importantly, they also have the ability to stimulate the growth of new blood vessels, a process known as angiogenesis.

The typical patient

Adipose tissue in particular is considered an ideal source for MSCs because it is largely dispensable and the stem cells are easily accessible in large amounts using a minimally invasive procedure. ADSCs have been used in several clinical trials looking at cell therapy for heart conditions, but most of the studies employed cells taken from relatively healthy young donors rather than sick, older ones — the typical patient when it comes to heart disease.

-We knew that aging and disease itself may negatively affect MSC activities, Dr. Dzhoyashvili said:

- So the aim of our study was to investigate how patient age affects the properties of ADSCs, with special emphasis on their ability to stimulate angiogenesis.

The results provide new insight

The team analyzed age-associated changes in ADSCs collected from patients of different age groups, including some with coronary artery disease and some without. The results showed that ADSCs from the older patients in both groups expressed various age markers, including shorter telomeres, and, thus, confirmed that ADSCs did age. Telomeres, the regions of repetitive DNA at the end of a chromosome, protect it from deterioration.

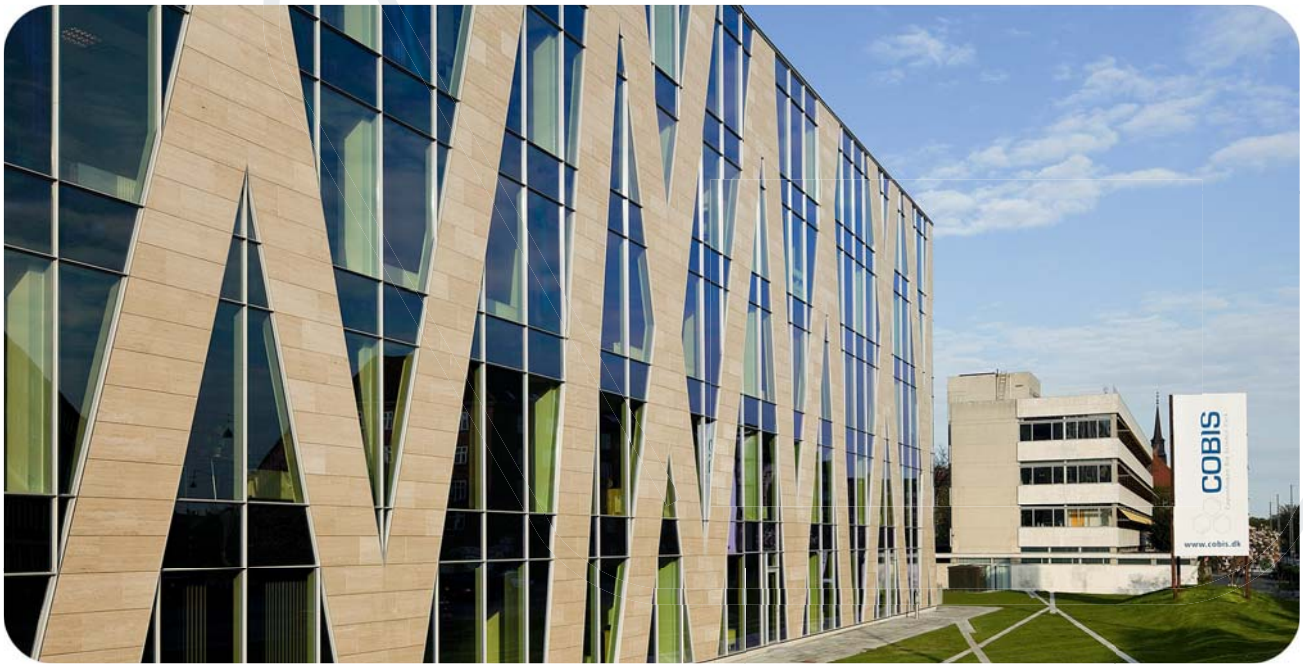
- We showed that ADSCs from older patients both with and without coronary artery disease produced significantly less amounts of angiogenesis-stimulating factors compared with the younger patients in the study and their angiogenic capabilities lessened. The results provide new insight into molecular mechanisms underlying the age-related decline of stem cells' therapeutic potential, Dr. Efimenko concluded.

- These findings are significant because the successful development of cell therapies depends on a thorough understanding of how age may affect the regenerative potential of autologous cells, said Anthony Atala, M.D., editor of STEM CELLS Translational Medicine and director of the Wake Forest Institute for Regenerative Medicine.

The full article, "Adipose-derived stromal cells (ADSC) from aged patients with coronary artery disease keep MSC properties but exhibit characteristics of aging and have an impaired angiogenic potential," can be accessed at: www.stemcellstm.com.

Read the scientific article in Current Biology: www.cell.com/current-biology/abstract/S0960-9822(13)01195-0

Cool location? Check!



Get more wow factor in your business today

In the beginning of 2014 Copenhagen Bio Science Park will open an additional 7000 m^2 of office and lab space, specifically designed for you to succeed! The space is exceptional. So why not join the most vibrant life science community in Denmark and start your adventure today. More than 32 companies have already done the same. You probably can't afford to miss out.

Give us a call today and learn more or check out www.cobis.dk for more information.

COBIS A/S
Ole Maaløes Vej 3
DK - 2200 Copenhagen N
+45 70 70 29 80
info@cobis.dk | www.cobis.dk

COBIS
Copenhagen Bio Science Park

And the winner is… Cancer research

Edit. by Viggo Mortensen

First presentation of Roche Science Award

The three winners of the first Roche Pharma Research & Development (pRED) Oncology Awards in the field of 'Novel Highly tumour-selective Membrane Targets for Antibody-based Cancer Therapy' have been selected. Krishna Chaitanya of the Oncological Institute at the University Hospital Zurich received the first prize for his outstanding studies on a radioisotope-coupled antibody against fibroblast activation protein (FAP), which provide a new approach to attacking tumor stroma. Tumor stroma consists of cells which support the growth of tumors. The 2nd prize went to Christian Jost of the Institute of Biochemistry at the University of Zurich for a completely novel concept enabling the inactivation of the HER2 receptor with small, non-antibody based binding molecules. Vineeta Bhasker Tripathi from the UCL Institute of Ophthalmology in London received the 3rd prize for her studies on the validation of Lrg 1 (leucine-rich alpha-2-glycoprotein-1) as a new target molecule for the suppression of blood vessel formation in tumors with the aid of function-inhibiting antibodies.

An extraordinary result

The competitors judged to be the ten best presented their studies in mid-November at the Penzberg Roche works to an audience of experts. A panel of university researchers and Roche experts chose the three victors. At the award ceremony in the evening, they received cash awards to the tune of 4,000, 2,000 and 1,000 euro.

- We are delighted by the outstanding quality and great number of submissions on this vital cancer research topic, commented Klaus Bosslet, Head of Discovery Oncology, and initiator of the award. - For the first award of a prize, this is an extraordinary result.

The pRED Oncology science award for outstanding European research work in the field of antibody-based cancer therapy was presented for the first time this year by the Discovery Oncology Unit in Penzberg. It honors innovative cancer research and emphasizes the commitment to more intensive collaboration with higher education institutions which Roche has been advocating for years.

Roche plans to continue the successful event in 2014 with a new exciting subject.

Roche pRED

Roche's Pharma Research and Early Development organization – Roche pRED – consists of some 2,500 scientists and clinicians with a shared vision of excellence in science, a proud heritage of healthcare innovation and a commitment to deliver new and effective medicines to patients. Working in partnership with Roche's world-leading Diagnostics Division, Roche pRED strives to make personalized healthcare a reality, and change the practice of medicine for future generations. Roche pRED focuses on four therapeutic areas: oncology, neuroscience, virology and cardiovascular-metabolism at six strategic sites worldwide. For more information: www.roche.com

Scientists show how cells protect their DNA from catastrophic damage

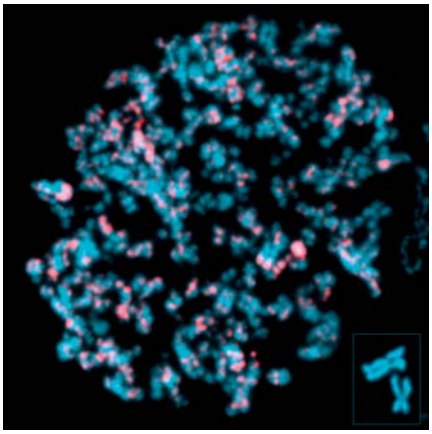
By Luis Toledo Lazaro

Researchers at the University of Copenhagen have unveiled a profound biological process that explains how DNA can be damaged during genome replication. In addition, the scientists developed a new analytical tool to measure the cell's response to chemo-therapy, which could have an important impact on future cancer therapy. The results are now published in the scientific journal Cell

An international team of researchers led by Professor Jiri Lukas from the Novo Nordisk Foundation Center for Protein Research, University of Copenhagen have unveiled a process that explains how DNA can be damaged during genome replication, due to the lack of a critical protein.
Cells need to keep their genomic DNA unharmed to stay healthy and the scientists were able to visualize the process of DNA replication and damage directly in cells with an unprecedented detail. They discovered a fundamental mechanism of how proteins protect chromosomes while DNA is being copied (a process called DNA replication), which relies on a protein called RPA. Cells have a limited amount of this protein, which they use as band aids to protect the DNA temporarily during replication. If they use up the RPA reservoir, their DNA breaks severely and cells are no longer able to divide.
- We now understand that many drugs used in chemotherapy are toxic against tumours because they make DNA replication difficult and force cancer cells to consume their RPA pool much faster than normal cells usually do. As a result, cancer cells are constantly at the verge of falling into a replication catastrophe, a condition from which they cannot recover, and which can be used as a powerful means to selectively eliminate cancer cells, says Luis Ignacio Toledo, the first author of this study.

Future impact on cancer diagnosis and treatment

In addition to helping other scientists to comprehend some of the most fundamental processes in cell physiology, the findings could have important implications for cancer diagnosis and treatment by helping understand, at the molecular level, what makes cancer cells different from normal cells.
- The relevance of our discovery is that it provides an explanation for a broad spectrum of previous scientific observations, which on the first glance seemed unrelated, but which we now show can be unified into a simple comprehensive model to understand how proteins protect DNA from catastrophic damage, concludes Luis Ignacio Toledo.
Read the full report in the scientific journal Cell at: www.cell.com/abstract/S0092-8674%2813%2901361-5



The scientists were able to visualize the process of DNA replication and damage directly in cells with an unprecedented detail

Five megatrends will transform the life-science sector in 2020

By Uffe Erup Larsen

There are many indications that life-science industries will be facing major changes in the coming years, as shown in a new report from courier company DHL. Together with the analytical firm Z_punkt, DHL has taken a look at the megatrends that will be affecting the sector in just a few years, and there is much in store for the companies involved

The report paints a picture of a sector that in the course of the next few years will be facing five major changes. First of all, the industry will be delivering certain products directly to consumers, as more and more will want to monitor their own health through different medical devices. The more widespread telemedicine and home care become, the more obvious it will become that certain medicines should be sent directly to those who need them. Although this is an area that requires regulatory intervention, it will eventually help to create additional health care savings.

Another trend is that the life-science sector will have an even greater need to be able to send packages in new ways. This is something that DHL Express is already noticing, as some customers need to send refrigerated biological samples, for instance. DHL has established a special department called Medical Express to handle consignments that must be kept refrigerated for up to 48 hours. Other companies in the sector will need to let their courier company manage their inventory in order to minimise delivery times to the customers.

Traceability ensures end-users

According to the report, 10% of all pharmaceutical products today are counterfeit, as are about 50% of the medicines sold through web sites. This means that within a few years end users will demand evidence of the products' origin and traceability of them throughout the supply chain. This increased visibility means that life-science companies will be able to better manage their expenses internally because they will have a larger overview of logistics costs. It is expected that manufacturers of generic drugs in particular will adopt this practice to further reduce expenses.

The fourth major change concerns urbanisation. According to a United Nations report, people will continue to flock to the cities and 58% of the world's population will be living in cities in 2025, compared to 52% in 2010. This will pose yet other infrastructure and logistics challenges for the life-science sector. In the cities modern lifestyles prevail, and that is the core of a consumer megatrend. There is a global tendency towards a more individualised society, where traditional relationships will decrease in importance. On the other hand, individual choices will increase, leading to greater health awareness. Thus there will be an increased demand for health care products, with subsequent logistic demands. Courier companies will also face demands for deliveries to previously remote locations in rural areas, opening new markets to them.

Finally, the fifth major change will be that life-science companies will want to be able to send everything from medicine to biological samples in one and the same consignment. It will just be a matter of taking into account that shipments will have to contain items at various temperatures – some will need refrigeration, others not. For these companies logistics will be crucial to differentiating themselves in the market and a key factor for achieving success.

DHL and its research partner Z_punkt, The Foresight Company, followed three steps in identifying the five megatrends and their importance. First, the most important megatrends were analysed. Next, the team looked at the most significant changes and growth tendencies in society, technology, politics and economics. Finally, the team drew their conclusions about the logistical consequences and areas where there is a need to take action.

The report, "Key logistics trends in life sciences 2020+", is written as a white paper and is filled with details about the reality the life-science sector will be facing within just a few years. It can be downloaded here: www.dhl.com/LSHC-Week.

EMA and FDA announces launch

Collaborative effort builds upon 2009 Good Clinical Practices Initiative

The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) has announced the launch of a joint initiative to share information on inspections of bioequivalence studies submitted to the EMA, the FDA and/or to the regulatory authorities in some EU Member States in support of marketing-authorisation applications for generic medicines. The joint initiative also introduces a mechanism to conduct joint inspections of facilities where these bioequivalence studies are conducted.
Successful demonstration of bioequivalence is the basis for the approval of generic medicines. Studies submitted in support of generic medicines applications must demonstrate scientifically that the generic medicine is "bioequivalent", or performs in the same manner as the innovator medicine. Regulatory authorities inspect facilities that conduct these studies to ensure data submitted to the agencies are reliable and of high quality.

Increased cooperation
This initiative will be carried out in the framework of the confidentiality arrangements established between the European Commission, the EMA, interested EU Members States and the FDA.
The EU Member States initially involved in this initiative are France, Germany, Italy, the Netherlands and the United Kingdom. Additional Member States are expected to join the initiative in the future.
Welcoming the initiative, Fergus Sweeney, Head of the EMA's Inspections and Human Medicines Pharmacovigilance Division, said:
- The progress of this initiative is testimony to increased cooperation and the hard teamwork of the inspection staff of all our agencies, helping us to better leverage our respective inspection resources. Globalisation of clinical trials means that we all rely on each other to assure the quality of bioequivalence clinical trials, and data from these, on which the approval of generic medicines, and therefore the health of EU and American patients, rely.
The bilateral inspection initiative includes an 18-month pilot phase, and builds on the successful 2009 EMA-FDA Good Clinical Practice (GCP) Initiative, designed to ensure that clinical trials submitted in marketing applications for medicines in the United States and Europe are conducted ethically and that the data generated by these trials are reliable.

MPI receives 3.5 million DKK from The Danish Market Development Fund

Medical Prognosis Institute A/S (MPI) has been granted 3.5million DKK from The Danish Market Development Fund for further development and clinical testing of MPI's Lung Prognosticator

The aim of the test is to identify lung cancer patients, who with high likelihood will have relapse after surgery allowing adjuvant therapy to be considered. It is expected that early treatment of this subgroup of patients will reduce the mortality.
Lung cancer is one of the most frequent cancer forms worldwide and 1.5 million patients are every year diagnosed with lung cancer representing more than 12% of all newly diagnosed cases of cancer. In USA lung cancer is the second most frequent form of cancer and lung cancer is the primary cause of death due to cancer for both men and women. In general, no adjuvant treatment is offered to patients diagnosed with early stages of lung cancer after surgery although approximately 30% of these patients will relapse in the following 5 years and eventually die.

One of the most feared cancer diseases
MPI has developed a gene-test (Lung Prognosticator), with the aim to identify lung cancer patients who with high likelihood will relapse after surgery allowing adjuvant therapy to be considered.
Hospitals in Denmark and USA have participated in the clinical testing of MPI's Lung Prognosticator, Immediately after this prospective clinical trial has been finalized, and if it is as positive as anticipated, the test will be introduced as CE-marked on the European market. At this stage the test will be further validated initially in collaboration with the Department for Lung Surgery, Copenhagen University Hospital, Rigshospitalet and later in collaboration with a minimum of five lung cancer centers (Europa, USA and Asia) testing 5000 patients, for identification of potential test modifications. These test centers can later be used as reference centers.
- Lung cancer is one of the most feared cancer diseases and our hope is that the MPI's Lung Prognosticator can help improve the survival of patients with a high risk of recurrence after surgery for early stage lung cancer, says Peter Buhl Jensen, CEO.
The grant does not change the financial guidance for 2013 and 2014.

Cancer Research Technology and Nuevolution Sign Multi-Target Deal

Cancer Research Technology (CRT), the commercial arm of Cancer Research UK, and Denmark-based drug discovery company Nuevolution A/S, have signed a collaboration deal to discover anti-cancer drug molecules targeting several key proteins

The collaboration aims to identify drug leads that block the activity of a number of challenging cancer therapeutic targets. This could lead to the development of first-in-class novel treatments for cancer patients.
Through the partnership, drug candidate molecules which home in on selected targets will be identified by screening millions of diverse small molecules using Nuevolution's proprietary Chemetics® technology. This uses innovative DNA labelling to enable small molecule drug screening – a method to identify small molecules which bind to a target protein – on an unprecedented scale.
- We are delighted to enter into this collaboration and believe that a strong synergy between the CRT and Nuevolution capabilities will provide for discovery traction on tough-to-drug targets, said Thomas Franch, CSO of Nuevolution.

A starting point for new options
CRT will provide expert information about the biology of the targets through Cancer Research UK's network of world-class scientists. The first targets have already been approved by CRT and Nuevolution for entry into the collaboration.
In addition, CRT through its internal Discovery Laboratories will provide drug discovery expertise including in-vitro screening assays and cellular activity assays for the target proteins, to select the most promising molecules to develop as potential drugs.
The further pre-clinical development of any promising small molecules identified will form the basis of a separate deal to be agreed in the future between CRT and Nuevolution.
- This deal is exciting as it will allow us to address a number of "low-tractability" cancer targets, which have proved difficult for ourselves and others to establish a foothold in drug discovery, said Dr Hamish Ryder, director of drug discovery at CRT's Discovery Laboratories.
- This important partnership combines CRT's drug discovery expertise and Cancer Research UK's strong academic research base with powerful technology from Nuevolution to enable 100s of millions of compounds to be rapidly assessed – which we hope one day will be a starting point for new options for cancer patients and increased survival.

Afsender: BJ Media, Tinggaardsvej 4, Valore, DK-4130 Viby Sj.

Magasinpost SMP
ID-nr. 46438