

ISPE NORDIC ANNUAL CONFERENCE 2016 AT INDUSTRIENS HUS

PRESENTATION SYNOPSIS 1/2

Presentation # 1

Authority inspection of GMP (Current and future challenges)

Thomas Vestergård Pedersen

EU GMP guidelines and regulations are under constant revision, improvement and expansion to meet new concepts and terminology in GMP, reflect increasing globalization, and meet new technical challenges in the pharmaceutical industry. All to ensure correct guidance for the industry to maintenance GMP compliance. This also requires changes in the way to perform GMP inspections of companies. What are the current and future challenges regarding this, seen from an authority perspective?

Presentation # 2

Industry challenges in a global market

Mette Rose Skaksen

Denmark has a strong and innovative healthcare and life science industry, which exports products worth more than 100 billion DKK every year. This makes the healthcare and life science industry a cornerstone in Danish economy. At the same time, there are challenges facing the industry, which may threaten the future growth potential. Mette Rose Skaksen will present the key recommendations from The Confederation of Danish Industry on how to improve the central framework conditions for the healthcare and life science industry in Denmark.

Presentation # 3

Factory of the Future with Information Technology

Sanna Gustavsson

Compared to 1913 when AstraZeneca's largest manufacturing site first opened its gates, today's technologies and ways of working is high tech science fiction. But let's fast forward a few years from now to see what the future pharmaceutical manufacturing site looks like, and how new information technology plays a key part. What can be applied to a manufacturing site, what is augmented reality and what's the point of letting shop floor equipment talk to each other? Let's take a look into the factory of the future.

Presentation # 4

3D printing of pharmaceuticals

Johan Peter Bøtker

3D printing provides an omnipotent platform for controlling the spatial distribution of both API's and excipients. This spatial control facilitates that the masses, positions and ratios of the API's and excipients can be changed independently and thus conveys control on factors such as release profiles. Furthermore, 3D printing may provide the possibility for substituting the API's without affecting the printing process, thus alleviating some of the work load in the early drug development phase.

PRESENTATION SYNOPSIS 2/2

Presentation # 5

Our Future Workforce

Flemming Dahl

A key to any company's success is continued growth of its product portfolio, including developing a healthy pipeline of new and innovative products. But with growth and innovation, also comes the need for new competencies. It is not only essential for a company to have world-class capabilities in chemical and biochemical development. We in the field of pharmaceutical engineering also need a workforce and leaders with the competencies to launch new products and innovate during this time of increasing global complexity and rapid change. Unfortunately, however, these types of engineering competences are scarce. As a result, Novo Nordisk has engaged in the public debate in Denmark and other countries to raise this issue with academic and government leaders. This presentation will focus on trends, challenges, and opportunities in the pharmaceutical engineering industry in regard to developing the workforce of the future, today.

Presentation # 6

Fighting the dragon with the nine heads

Jesper Hildebrandt Brix

Every minute three people die from tuberculosis (Tb). It is the number one killer among infectious diseases, 1.8 million died in 2015. The countries with the highest Tb burden, lack access to both diagnostics and the drugs needed to treat the growing numbers of patients and respond to the drug resistant form of tuberculosis, which exist worldwide today. Something urgently needs to change if we are to stop the spread of tuberculosis.

Jesper Brix talks about how Médecins Sans Frontières (MSF) works with tuberculosis, from his own experience working in the Russian prisons in Siberia to MSF latest attempts to find new ways forward for tuberculosis prevention and treatment.

Presentation # 7

Recombinant antivenoms against snakebites

Andreas Hougaard Laustsen

From an early age, Andreas has been involved in entrepreneurship based on biotechnological research and he is recognized as Denmark's Coolest Engineer and one of the Top 10 biotech entrepreneurs under 30 years of age in Europe. At the age of 24, he was part of starting the biotech company, Biosyntia, involved in synthetic biology and metabolic engineering, and a year later he co-founded the company, VenomAb, focusing on developing novel antivenoms against snakebite. Alongside his entrepreneurial activities, Andreas pursued a PhD at the University of Copenhagen within recombinant antivenoms against snakebite, which concluded in May 2016, whereafter Andreas has been a Postdoctoral Fellow at the Technical University of Denmark. In his presentation, Andreas will present the challenge of snakebite, his vision of developing recombinant antivenoms, and how he has been able to bridge academia with industry and startup.