Live Online Conference on 22 November 2021

Optimization and Automation

This Live Online Conference is part of LIVE ONLINE PharmaLab 21
Analytics·Bioanalytics·Microbiology
22-26 November 2021

Highlights

- Laboratory and Method Optimisation
- Continous Improvement
- Digitalization in the Lab
- KPIs for Performance-Measurement

Speakers

Dr Karl-Heinz Bauer, Boehringer Ingelheim

Ulla Bondegaard, Novo Nordisk

Fábio Brito, LEF

Miriam Guest, AstraZeneca

Laurent Leblanc, bioMérieux

Robert Lutskus, Lonza

Lars M. H. Reinders, University Duisburg

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www.pharmalab-congress.com

Official Media Partners 2021:
European Biotechnology Life Sciences and Industry Magazine
EPR European Pharmaceutical Review

Optimization and Automation

22 November 2021, 11.00 - 17.30 h CET

Objectives

The aim of this Live Online Conference is to show possibilities to optimize the organization of a laboratory and to reduce costs. The topics LEAN, both for the laboratory and laboratory management and the optimization of structures and processes in the laboratory, are addressed. Furthermore, the possibilities of automation are presented and the benefits that can result from the optimization of the method portfolio. Equally modern approaches to cost savings through reduced testing and reduced sampling while maintaining GMP compliance will be presented.

Background

The pressure that the pharmaceutical industry is under today to reduce costs and increase efficiency and effectiveness applies equally to analytical laboratories. Often waiting for the results of quality control is still a speed-limiting step in the entire production process.

Many modern tools such as LEAN, Six Sigma, CIP, etc. are increasingly used to increase the efficiency (also) of analytical laboratories.

The correct recording and evaluation of the "Key Performance Indicators" (KPIs) plays a decisive role in this. Which of these factors are really "key", which ones can be dispensed with?

With this Live Online Conference, managers and employees in the laboratory learn tools for more effective and efficient control of laboratory activities.

Topics are:

- LEAN in QC
- Key Performance Indicators (KPIs)
- Optimization of laboratory processes - practical examples
- Cost-efficient design of a laboratory
- Case Studies for Laboratory Automation
- New analysis methods for the optimization of processes in the laboratory
- Reduced sampling and reduced scope of testing in the incoming goods inspection of active and auxiliary materials

Target Group

This Live Online Conference is aimed at laboratory managers and laboratory staff in the pharmaceutical industry who work in the areas of incoming goods inspection, finished goods inspection and analytical development. Also addressed are laboratory managers in the field of pharmaceutical active ingredient and excipient production and contract laboratories. The contents will also be of great interest to competent persons according to §14 AMG and to heads of quality control as well as to employees from the QA department

Programme

Continous Improvement & Idea Management Process (CIP & IMP)

- Sustainable contributions to laboratory optimizations

Dr Karl-Heinz Bauer, Boehringer Ingelheim

Digitization of Workflows and Method Developments in a Pharmaceutical Testing Laboratory

- Presentation of a quality control workflow that has been fully digitized
- Method development using a Quality-by-Design (QbD) approach.
- Comparison of a manual and digitalized workflow for the content determination of patient-specific preparations (incl. comparison with European Pharmacopoeia).
- Digitization using existing infrastructure such as scales
- Development of a wipe sampling based monitoring method for trace analysis of monoclonal antibodies using a quality-by-design (QbD) approach.

Lars M.H. Reinders, IUTA

Efficient Cleaning Techniques: A Good Starting Point for a Successful Trace Metal Analysis

- Contamination is one of the biggest causes of concern and difficulty in trace metal analysis. High blanks are at the root of most invalid or misleading results from this type of analysis.
- Metallic elements are not biodegradable, so their presence, when undue, remains over time. It is necessary to achieve a high cleaning efficiency of laboratory material, as the detection levels of the most common analytical equipment can easily reach the ppb and ppt level.
- The most common technique for removing elements from the analysis material is a process of passivation of the material in an acidic solution of high concentration. But is this process enough?
- Would it be efficient to apply an automatic washing method, developed specifically for this analytical application? How much more efficient would it be compared to the passivation process? And the possibility of running a combination of the two processes?

Fábio Brito, LEF - Infosaúde

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KPIs for Performance-Measurement
- Definition of KPIs, Strategy, Balance Scorecard
- Goals for KPIs
- Examples for QC/Laboratory Performance Parameters & Balanced Scorecards

Dr Karl Heinz Bauer, Boehringer Ingelheim

IT / Computers in the Lab
Ulla Bondegaard, NovoNordisk

The Integrated, Automated Lab of the Future
- Importance to have a long term strategy to prepare for the QC lab of the future.
- What is the vision for the lab of the Future?
- Driving factors for investing in automation
- How digitalization is key to achieving this.
- Factors to consider when selecting solutions ensuring integration

Robert Lutskus, Lonza

Accuracy of Human Visual Inspection in Pétri Dishes Enumeration
- Introduction to a methodology to evaluate the limit of detection of the huamn eye in Petri dishes enumeration
- use of calibrated beads (from 50µ to 500µ)
- different laboratories and 12 operators
- Evaluation of the accuracy of Petri dishes enumeration on real microorganisms by trained pharmaceutical operators
- 4 pharmaceutical companies
- pharmacopoeias strains + wild in house isolates (from 5 to 50 CFUs)

Laurent Leblanc, bioMérieux

Microbial Identification: Maximising the Data Value of Pharmaceutical Flora
- Multi-site approaches and harmonising microbial identification – the benefits and the challenges
- Use of data monitoring and trending cleanroom isolates
- Using microbial identification trends to support the adoption of alternative micro methods

Miriam Guest, AstraZeneca

Speakers

Dr Karl-Heinz Bauer, Boehringer Ingelheim, Germany
Dr. Bauer holds a PhD in pharmaceutical engineering and has been with Boehringer Ingelheim for more than 25 years. He has held various senior management positions in quality assurance, quality control and pharmaceutical manufacturing. During this time, he successfully introduced the Continuous Improvement Process into the quality department. In addition, he was responsible for the balanced scorecard of the quality unit. Since January 2020, he has taken over a strategic, international quality management position. In addition to that, Dr Bauer works now for many years as a speaker, consultant and coach in the pharmaceutical industry.

Ulla Bondegaard, Novo Nordisk, Denmark
Ulla Bondegaard (M.Sc. Chemical Engineering) has many years of experience in management of quality control laboratories covering a wide range of analytical techniques (HPLC, GC, AAS, AA, IR, Elisa, etc.). Currently she is responsible for maintaining cross-organisational (and cross-country) laboratory processes in Novo Nordisk, including general laboratory GMP, handling of laboratory computerised systems and transfer of analytical procedures.

Fábio Brito, LEF, Portugal
Fabio has a degree in Chemical Engineering. During his career he has been in roles related to pharmaceutical quality control, drug stability, and pharmacological techniques in general.
Fabio is currently working as an Analytical Method Development and Validation Technician at the Trace Metal Laboratory of LEF, specifically in the ICP-MS technique.

Miriam Guest, AstraZeneca, UK
Mirian has worked in pharmaceutical development for over 20 years, She is leading AstraZeneca's modernisation of microbiology technology strategy, as well as their global Micro Forum, which connects all of our operations sites' microbiology laboratories across the globe.

Laurent Leblanc, bioMérieux, France
Laurent is R&D manager for bioMerieux' Healthcare business. He holds a Master's degree in Biotechnology from the University of Limoges, France. For the last 15 years, he worked in several biotechnology companies and, before joining bioMerieux in 2008, worked in microbiological quality control in the pharmaceutical industry. He is now involved in designing and bringing to the market the new innovative and efficient microbiological solutions dedicated to the pharmaceutical and cosmetic industries.

Robert Lutskus, Lonza, USA
Robert Lutskus studied at the Delaware University. Currently he is Associate Director, Commercial Operations - Lonza Informatics, Before this he was is the Global Product Delivery Manager for MODA™ EM. He has been a MODA SME for over 8 years, and working in QC laboratories for over 15 years.

Lars M. H. Reinders, University Duisburg, Germany
Lars started his PhD at the Faculty of Chemistry of the University of Duisburg-Essen after studying instrumental analysis at the Niederrhein University of Applied Sciences. His research focuses on the development and validation of analytical methods for quantification and identification of monoclonal antibodies.

Easy Registration

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Date of the Live Online Conference

Monday, 22 November 2021, 11.00 – 17.30 h CET

Technical Requirements

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Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.pharmalab-congress

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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Registration Options

I want take part in:

With a one day/two day/five day ticket for the PharmaLab Live Online Conferences you can attend the Live Online Conference offered that day/s.

Please mark your ticket:

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Please mark the days you want to attend:

- ❑ 22 November: Optimisation and Automation
- ❑ 23 November: Validation of Analytical Methods and Life Cycle Management of Analytical Procedure
- ❑ 24 November: Alternative- and Rapid Microbiological Methods
- ❑ 25 November: Endotoxin and Pyrogen Testing (Day 1)
- ❑ 26 November: Endotoxin and Pyrogen Testing (Day 2)

If the bill-to-address deviates from the specifications on the right, please fill out here:

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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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