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Next Generation Sequencing (NGS)

25 June 2024, Munich, Germany

A Pre-Conference Workshop of the European Microbiology Conference
26/27 June 2024, Munich



This conference is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find more details at www.gmp-certification.eu

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Overview

Objectives

This workshop will deal with the existing and announced relevant regulations in pharmacopoeias and guidelines and will present the collected comments of the ECA NGS Task Force on the planned Draft Ph.Eur. 2.6.41, which is to be published shortly. In addition, experts from industry, laboratories and service companies will report on their experiences with NGS.

Background

Next Generation Sequencing (NGS) has taken on an important role in drug control. This technology enables the rapid and precise analysis of DNA and RNA sequences. In terms of drug control, NGS can be used to verify the composition of drugs, including the identification of active ingredients, impurities or potential allergens.

NGS also enables the analysis of microorganisms in drugs, which is important to detect impurities that could affect the safety and efficacy of a drug. In addition, NGS can help identify genetic variants in patients that could influence the response to certain drugs, contributing to personalized medicine.

Overall, NGS enables a comprehensive analysis of drugs and can help to improve their quality, safety and efficacy.

Programme

Draft Ph.Eur. 2.6.41 – Content and Comments

Dr Sven M. Deutschmann, Roche & Dr Oleg Krut, PEI

- Introduction
- Comments from ECA “NGS”-Task Force

Revision (R2) of Guideline ICH Q5A on Viral Safety Evaluation of Biotechnology Products

Dr Astrid Schwantes, PEI

- Updates in ICH Q5A(R2) with focus on the testing strategy and testing methods (including NGS)
- NGS application to different biomedical products

Use of NGS to Identify Relationships in the Legal Context of Food Safety Controls

Coen van der Weijden, Netherlands Food and Consumer Product Safety Authority

- NGS typing to identify relationships between food pathogen isolates.
- The legal context of using NGS in official controls for food safety.
- Connecting data from the human and food domain in the Netherlands and internationally.

GMP-Compliant Analysis of NGS Data for Detection of Contaminants, Identification of Bacterial and Fungal Strains, and Typing

Dr Stefan Emler, Smart Gene

- Apps for easy processing of NGS datasets by non-bioinformaticians in routine laboratories
- Meaningful, accurate and reproducible results also for QM/QC tests in biopharmaceutical production

- AI-curated proprietary “Centroid” reference sequence databases with validated content and up-to-date nomenclature to support high-resolution identification of >16,000 bacterial species and >40,000 fungal species
- User protocols and audit trails for full traceability of analyses

NGS Strategies from Sample to Report for Microbial Identification and Viral Contamination Detection in Pharma

Caroline Rosseel, Thermo Fisher Scientific

- Ion Torrent NGS Technology Overview
- The Advantage of NGS on Microbial ID and on Viral Safety Testing
- Ion Torrent NGS Technology Approach for Microbial ID and for Viral Safety Testing
- Analysis Solutions with Regulatory Compliance

Diversity of *S. epidermidis* – NGS Implementation in a GMP environment

To be announced

The way NGS is Shaping the Future of Food-Borne Outbreak Investigations in the Netherlands

Charlotte Verbart, Netherlands Food and Consumer Product Safety Authority

- Collaboration between Public health and Competent Authority on food safety.
- Traditional methods used in food-borne outbreak investigation, illustrated by the example of an outbreak of listeriosis.

Short Poster Presentation: Bacterial community structure and dominant species in pharmaceutical manufacturing water revealed by high-throughput sequencing

Saori Shikama, Takeda

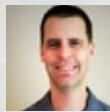
- Culture independent bacterial community structure analysis at cold WFI system
- High-throughput sequencing that targets full length 16S rRNA gene effectively identified dominant species

Case Studies, Data and Experience on NGS

Doug Botkin, Charles River Laboratories

- Current NGS applications for QC Micro
- Future NGS applications for QC Micro
- NGS challenges

Speakers



Doug Botkin

Charles River Laboratories
Technology and Market Development Manager



Dr Astrid Schwantes

Paul-Ehrlich-Institut, German Federal Agency for Vaccines and
Biomedicines
Regulatory Assessor Virology



Dr Sven M. Deutschmann

Roche Diagnostics
Head of Global ASAT Adventitious Agent Testing &
Alternative Microbiological Methods



Saori Shikama

Takeda



Dr Stefan Emler

SmartGene
Founder and Director



Coen van der Weijden

Netherlands Food and Consumer Product Safety Authority
Senior/Coordinating Inspector Microbiological Food Safety



Dr Oleg Krut

Paul-Ehrlich-Institut, German Federal Agency for Vaccines and
Biomedicines
Lead Microbiological Safety



Charlotte Verbart

Netherlands Food and Consumer Product Safety Authority
Senior Advisor on Microbiological Food Safety



Caroline Rosseel

Thermo Fisher Scientific
Sr. Product Specialist NGS

Dates

Pre-Conference Workshop – Next Generation Sequencing (NGS)

Tuesday, 25 June 2024, 09.00 - 17.30 h
(Registration and coffee 08.30 - 09.00 h)

European Microbiology Conference

Wednesday, 26 June 2024, 09.00 - 17.30 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 27 June 2024, 09.00 - 17.00 h

All times mentioned are CEST.

Venue

HYPERION Hotel München
Truderinger Straße 13
81677 München

hyperion.muenchen@h-hotels.com

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

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

Fees (per delegate plus VAT)

Pre-Conference Workshop – Next Generation Sequencing (NGS)

ECA Members EUR 990.-
APIC Members EUR 1,040.-
Non-ECA Members EUR 1,090.-
EU GMP Inspectorates EUR 545.-

Fee includes lunch and all refreshments.

European Microbiology Conference

ECA Members EUR 1,790.-
APIC Members EUR 1,890.-
Non-ECA Members EUR 1,990.-
EU GMP Inspectorates EUR 995.-

Fee includes dinner on 26 June, lunch on both days and all refreshments.

European Microbiology Conference AND Workshop

ECA Members EUR 2,480.-
APIC Members EUR 2,580.-
Non-ECA Members EUR 2,680.-
EU GMP Inspectorates EUR 1,340.-

Fee includes dinner on 26 June, lunch on all three days and all refreshments.



The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference Language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG

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Germany

Reservation Form (Please complete in full)

- ☐ Pre-Conference Workshop – Next Generation Sequencing (NGS), 25 June 2024, Munich, Germany
☐ European Microbiology Conference, 26/27 June 2024, Munich, Germany
☐ European Microbiology Conference AND Workshop, 25-27 June 2024, Munich, Germany

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General terms and conditions

If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %
- Cancellation until 3 weeks prior to the conference 25 %
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airline penalties or other costs incurred due to a cancellation. **Terms of payment:** Payable without deductions within 10 days after receipt of invoice. **Important:** This is a binding registration and above fees

are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022). German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.