

Barcelona- 6th July 2017

EFFICIENT MICROBIOLOGY

09:00h

Documentation delivery

09:30h

Symposium introduction

Ana Fuertes – Iberia Industry Head, bioMérieux Industry

09:40h

DATA INTEGRITY

Yves Samson - Kereon AG Director

- Introduction to Data Integrity
 - Data life cycle
 - ALCOA+: Integrity criteria
 - Regulatory requirements
 - Paper versus hybrid versus electronic systems
- User account management & Application configuration
 - Segregation of duties
 - Application configuration
 - User account management
 - Do's and don'ts
 - Review of system users and privileges

Coffee break

- Audit trail
 - Technical requirements
 - Supporting system functionalities
 - Audit trail vs. system logs
 - Prerequisite for an efficient audit trail implementation
 - Audit trail review
- Analysis of FDA warning letter
- Conclusion - 12 tasks of data integrity

13:15h

bioMérieux. Creating culture of Data Integrity

Antoine Bloch - Marketing Health and Personal Care Director, bioMérieux Industry

EviSight™ Compact. Your automated traditional method

Angelika Horejs - Global Solution Manager EviSight, bioMérieux Industry

Laurent Leblanc - Health and Personal Care R&D Manager, bioMérieux Industry

Showroom: EviSight™ Compact – Vitek2™ compact – BacT/ALERT™ 3D

15:00h

Cocktail



Yves Samson
Kereon AG
Basel, Switzerland



Automation and system engineer with over 25 years experience, including 11 years as regulated user, Yves is the founder of Kereon AG. He supports his customers as consultant, trainer, and e-compliance auditor. He is member of GAMP Europe Steering Committees, chairman and cofunder of GAMP Francophone. He edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

Location:
NH Collection Constanza
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