

Madrid - 4<sup>th</sup> 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:**  
**Hotel Novotel Madrid Center.**  
**Calle de O'Donnell, Nº 53**  
**MADRID**

