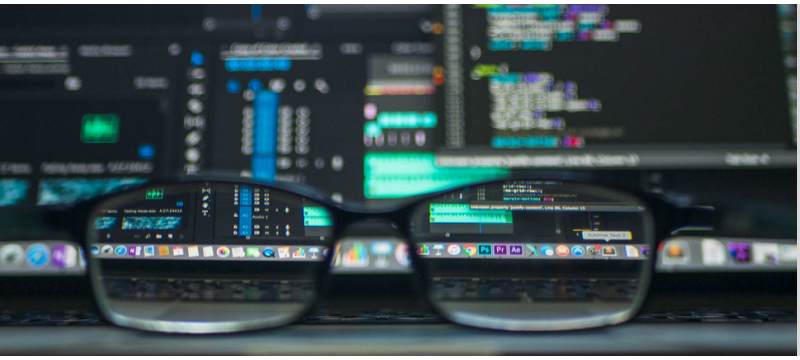
61° SIMPOSIO AFI
RIMINI 8-9-10
GIUGNO 2022

Associazione Farmaceutici Industria
Società Scientifica

WORKSHOP WEBINAR

DIGITAL JOURNEY IN PAPERLESS VALIDATION



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TUESDAY - 14TH JUNE 2022 - HOUR 10:00/11:00

Digital transformation involves every level of your company's operations, from simple process computerization to artificial intelligence capable of automating information exchange. This transformation affects documentation, management flows and compliance procedures and is possible through the right tools that allow you to optimize and improve every aspect of their management.

In this move toward Pharma 4.0, digitized validation represents one of the fundamental steps.

Validation is a key factor within the pharmaceutical world: all the equipment, computer systems, processes, utilities used for the manufacture of medicinal products need to be validated to be compliant with the GMP regulation: "It is a GMP requirement that manufacturers control the critical aspects of their particular operations through qualification and validation over the life cycle of the product and process." (Annex 15 Eudralex).
What is the goal of this workshop and how can these challenges be addressed?
The main objective is to present an innovative approach that combines technological advancement and the know-how of GxP experts to support the qualification and validation processes with a vision aimed at Industry 4.0.
Digitizing your validation processes is more than just eradicating paper. A true digital transformation process will leverage the power of data, enforce best practices and standards, and enable data integrity governance in the corporate validation process.
Electronic validation guarantees the digitization and optimization of processes and time reduction, while ensuring greater compliance. So, why continue to approach a process considering a workflow comprising creation, printing and compilation of paper documentation instead of exploiting the potential that technological development offers us?

SPEAKERS/CHAIRMAN

Chiara Bulgheresi - Akka & Modis
Emmanuel Cansino - ValGenesis
Nicola Lepore - Akka & Modis
Bo Olsen - ValGenesis
Alessandro Regola - AFI
Sonia Suardi - Akka & Modis

PROGRAM

Chairman: **Alessandro Regola (AFI)**

10:00 – 10:10 **Introduction to the topic of the Webinar**
Alessandro Regola (AFI)

10:10 – 10:20 **Digital transformation: maturity Model**
Sonia Suardi (Akka &Modis) / Bo Olsen (ValGenesis)

10:20 – 10:50 **The digital approach to the validation and calculation of ROI**
Emmanuel Cansino (ValGenesis)

10:50 – 11:00 **Q&A**
Nicola Lepore (Akka & Modis) + Chiara Bulgheresi (Akka & Modis)

About AKKA & Modis
AKKA & Modis, are now Akkodis, is a global leader in the engineering and R&D market that is leveraging the power of connected data to accelerate innovation and digital transformation. With a shared passion for technology and talent, 50,000 engineers and digital experts deliver deep cross-sector expertise in 30 countries across North America, EMEA and APAC. AKKA & Modis offers broad industry experience, and strong know-how in key technology sectors such as mobility, software & technology services, robotics, testing, simulations, data security, AI & data analytics. The combined IT and engineering expertise brings a unique end-to-end solution offering, with four service lines – Consulting, Solutions, Talents and Academy – to support clients in rethinking their product development and business processes, improve productivity, minimize time to market and shape a smarter and more sustainable tomorrow. AKKA & Modis is part of the Adecco Group.
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About ValGenesis
ValGenesis, Inc. is the creator of an innovative software platform that serves as a foundation for managing compliance-based validation activities in life science companies. ValGenesis, Inc. is the provider of the first enterprise application that manages the corporate validation lifecycle process. This solution is fully compliant with U.S. FDA 21 CFR Part 11 and Annex 11 requirements. As the first fully paperless solution for electronic management of validation execution and approval, ValGenesis was selected by an industry peer review committee to receive the Parenteral Drug Association (PDA) New Innovative Technology Award in 2005.
For more information, visit **www.valgenesis.com**

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Participation is free upon registration for AFI and non-AFI Members.

Deadline registration: the online registration will be available until 5 pm of the day before the webinar.

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