



M4Dconf 2022

IMEKO TC 6 – First International Conference on
Metrology and Digital Transformation

19. – 21. September 2022



Berlin, Germany

SPECIAL SESSION

Digitalization of Metrology in Pharma Industry

The pharmaceutical industry as a whole (including the rapid development of new vaccines) is heavily regulated and competitive at the same time. The regulatory issues and its high risk products make it often the leader among manufacturing industries in adopting new technologies which then bring new regulations. US FDA Title 21 CFR Part 11 (1997-) is the most famous example of the now globally accepted code of regulations on electronic records and electronic signatures. And right now, moving from electronic towards digitalized metrology brings a whole new set of possibilities and challenges to GxP guidelines, ALCOA, and relevant data that has huge impact on product quality and patient safety. Especially important part of that is data integrity, and the main challenge is how to fulfill requirements to be compliant and produce data relevant for making quality decisions.

SESSION ORGANIZERS

- › Sinisa Prugovecki (LorisQ)
- › Tatjana Jurkovic

IMPORTANT DATES

- › Extended Abstract Submission Deadline:
15 March 2022

WEBSITE & CONTACTS

www.m4dconf2022.ptb.de
m4dconf2022@ptb.de

SESSION TOPICS

- Digital metrology records
- Quality relevant metrological data
- Digitalization of GxP records
- Digitalization and ALCOA principle in metrology
- Data integrity
- GxP Validation of Metrology Equipment
- Trending
- Risk assessment: what could go wrong with the digital system which produces GxP records, mitigation measures
- Corrective and preventive actions
- Storage of GxP relevant digital records
- Digital data (records) backup and restore
- Digital metrological records, audits and audit findings



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Sinisa Prugovecki

Born on World Metrology Day, exactly 101 years after the signing of the Metre Convention. For a while, he tried to dodge its destiny by graduating in Astrophysics on the University of Zagreb in 2001., but after his brief scientific career in that field, he ended up in metrology (naturally). In 2008. he founded his first startup – Metroteka lab, which quickly grew to become a local leader in ISO/IEC 17025 accredited calibration, and roughly 10 years later he started his second one, which is of course – LorisQ.

In the meantime, he served on the boards of directors of Croatian Metrology Institute, Croatian Society for Quality, and is still doing time on the board of directors of Croatian Metrological Society. He is also a member of IMEKO TC6 (Digitalization).

Tatjana Jurkovic

Tatjana is an industry expert in the field of Quality Assurance in Pharma and related industries and is a ECA Certified Computer Validation Manager. Her experience includes being a Validation (Qualification) Lead in implementation projects and Head of Laboratories on global company level. Her main fields of interest are improvement of Quality Management System processes in accordance with regulatory requirements and quality system requirements, process automatization and especially improvement/development of computer systems.



SUBMISSION OF ABSTRACTS

- › Submission of abstracts for this Special Session are handled by the IMEKO Conference platform:
<https://conferences.imeko.org/event/2>
- › The deadline for submission of abstracts is 15th March 2022
- › Response to authors is scheduled for 31st May 2022