MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

SID& GP

GMP

10th PAN-RUSSIAN GMP CONFERENCE

Digital Transformation in the Pharmaceutical Industry

Michael Pelosi

Astellas Mandatory Disclaimer

"The speaker is a paid employee of Astellas. This presentation is intended for informational purposes only and does not replace independent professional judgment. This presentation is not intended to provide medical or legal advice. Statements of fact, positions taken and opinions expressed are those of the speaker individually and, unless expressly stated to the contrary, do not necessarily reflect the opinion or position of the speaker's employer, Astellas, or any of its subsidiaries and/or related entities."

Overview

- Introduction
- Inter-Company Quality Analytics (IMPALA) Consortium
- Revolutionizing Pharma Quality Assurance: AI Embedded Capabilities in QMS
- AI and the Quality Professional
- Challenges & Consideration
- Summary

The Inter-Company Quality Analytics (IMPALA) Consortium

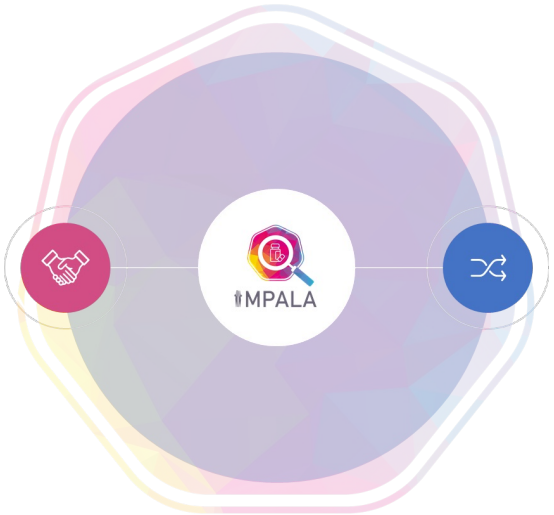
10th PAN-RUSSIAN GMP CONFERENCE

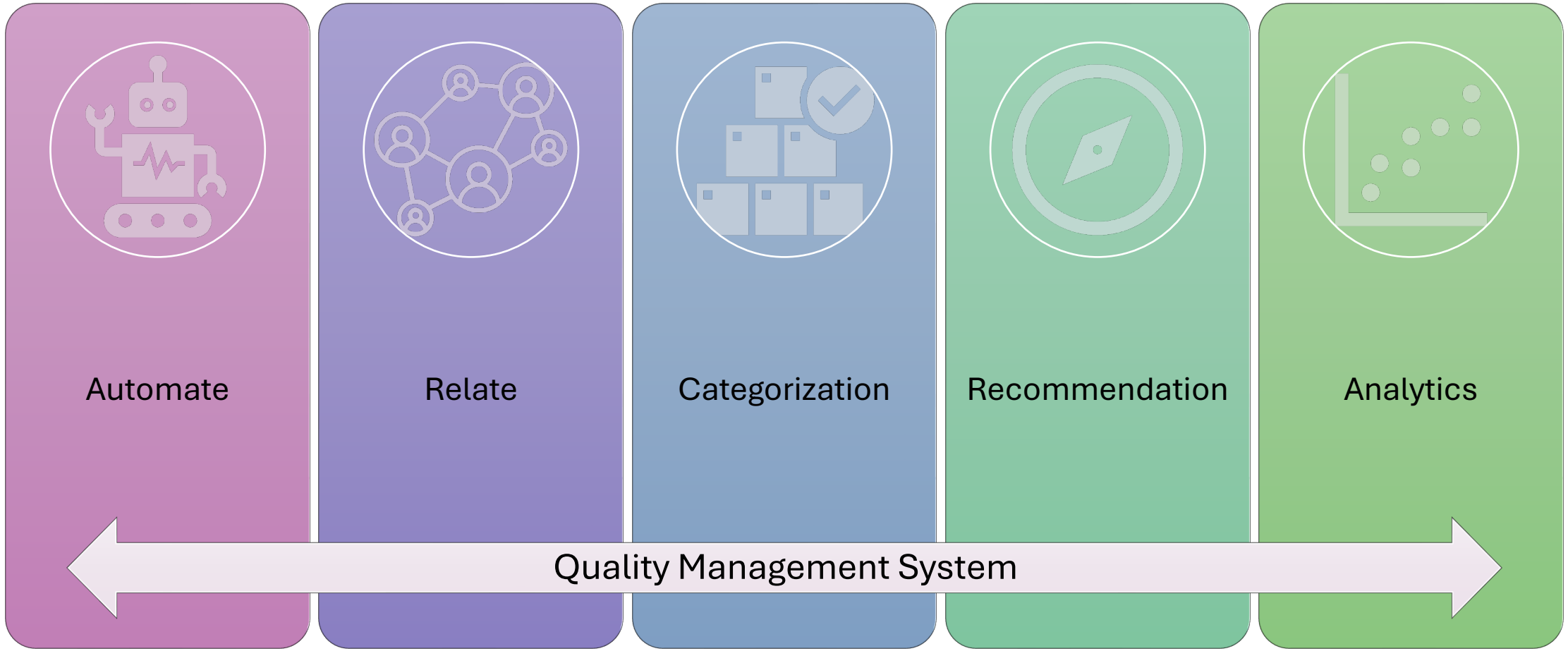
Mission

We are transforming biopharmaceutical quality by co-developing open-source tools, methodologies, and best practices to influence standards and by collaborating with biopharma industry leaders and health authorities to share knowledge and gain industry-wide adoption of digital and advanced analytics methodologies to enhance quality activities.

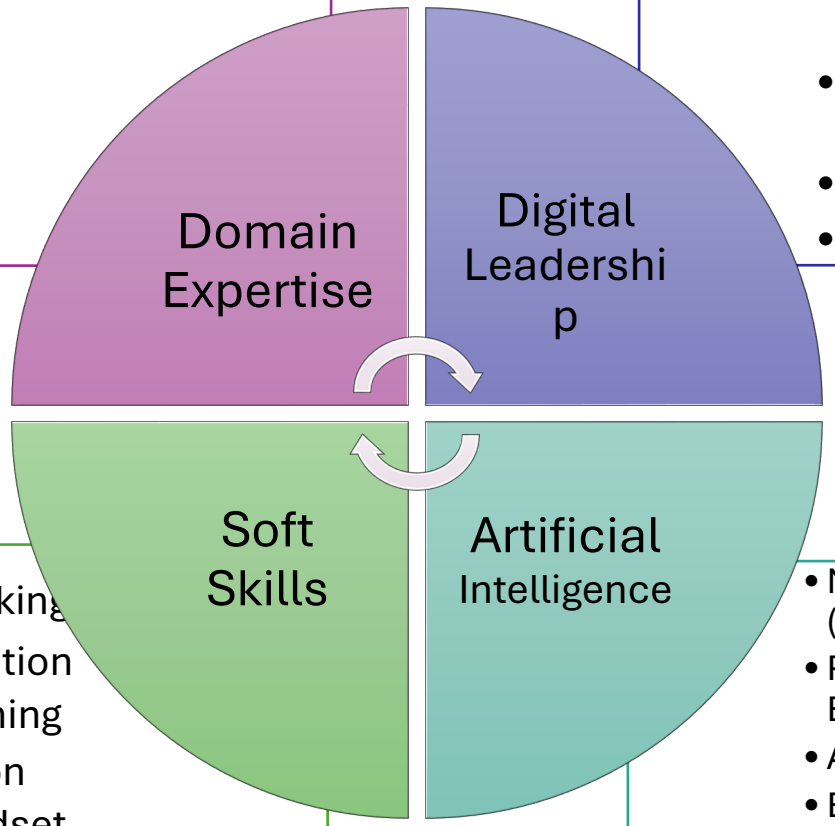
Vision

By applying digital and advanced analytics methodologies at scale for biopharmaceutical quality, we bring life-changing medical solutions to patients faster.




Automate
Relate
Categorization
Recommendation
Analytics
Quality Management System

AI and the Quality Professional

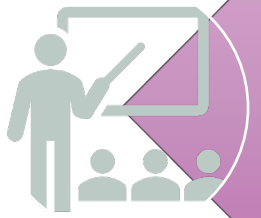


- Health Sciences
- Quality
- GxPs
- Regulatory

- Data Storytelling
- Digital Fundamentals
- Data Analytics
- Experimentation

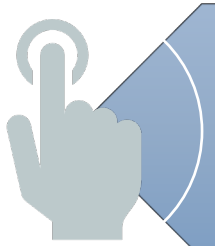
- Critical Thinking
- Communication
- Active Listening
- Collaboration
- Growth Mindset

- NLP, LBasics of AI (ML, LM, GenAI)
- Prompt Engineering
- AI workflows
- Emerging Regulations



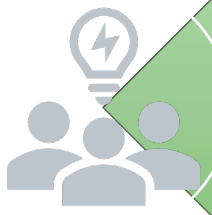
Training Programs

- Bridge the knowledge gap



Hands-on Experience

- Use practical applications of AI



Collaboration

- Encourage teamwork and share knowledge

Challenges & Considerations

Ethical Considerations

- Addressing bias and data privacy

Regulatory Compliance

- Ensuring systems and processes meet regulations & standards

Technical Challenges

- Integration with legacy systems

Summary

- Health authorities are providing guidelines and regulations for the ethical use of AI in drug development and medical devices, emphasizing transparency and patient safety.
- Building an effective AI use case involves identifying problems worth solving, scoping projects, and iterating on solutions to maximize value.
- It is important for QA professionals to develop complimentary skills to adapt to the changing landscape brought about by AI technologies, ensuring they are equipped to handle these advancements.
- As AI levels the field of knowledge accessibility, it will increase the importance of humans-in-the-loop and critical thinking.