

Welcome to the Life Sciences Track

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Life Sciences Industry Team

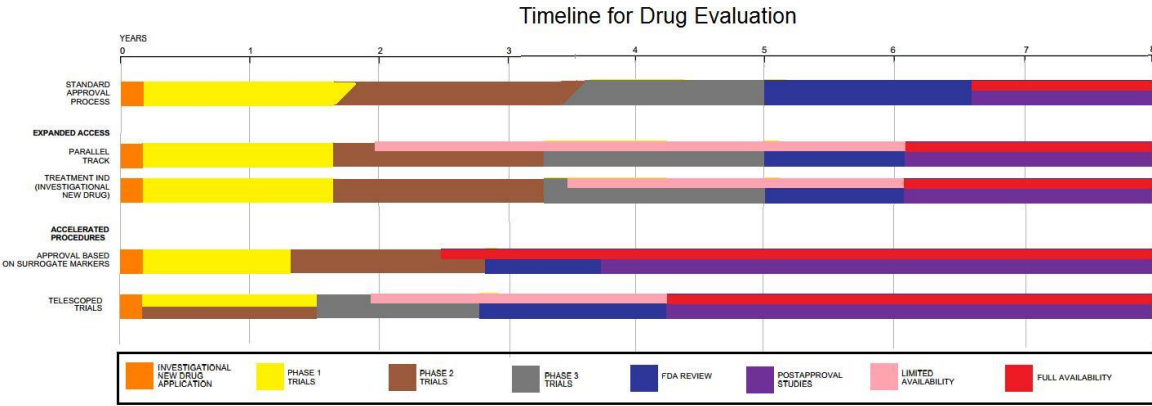
Petter Moree
Industry Principal



Bryan Pope
Industry Champion and Technical Advisor



Covid19 and Life Sciences industry



Data play a key part for scale-up, transfer and manufacturing as it all driven by knowledge management

- **79** companies are currently in the race for a vaccine or treatment for Covid19 disease.
- **9** of these are already in Clinical Phase 1 and a few in Phase 2
- The challenge is the time to patient, **6 000 000 000** patients

Covid19 challenges

- Cost of drugs and raw materials
- Supply Chain
- FDA policies
- Data and Analytics
 - Integrating siloed data and derive insights
 - Infrastructure to leverage the power of Big Data
 - Leveraging unstructured data
 - Advance insights from clinical trails
 - Data privacy
- Digital Health
- Primary and Secondary markets (DS & DP)



Taking Stock


Around **60-70%** bulk drugs & APIs for manufacturing antibiotics come from Hubei province, the capital of which, Wuhan, is the epicentre of coronavirus outbreak

Common antibiotics like metronidazole & chloramphenicol apart from Vitamin B1, B6 are made using ingredients from Hubei province

With airlines suspending flights, drugs like steroids may also see shortages in India

Pharmaceutical companies may face disruptions in case China continues lockdown beyond Feb 10

DoP committee has asked cos to provide specific details on stock inventory





Reporting

eBR

RbE

Data Integration

OOS/NC investigation



Tech Transfer

Knowledge
Management

QbD & Design Space

Risk Assessment



Operational Excellence

PAT & Real-time
decisions

KPI/OEE

Energy & Maint Mngnt



cGMP
21 CFR Part 11
Data Integrity

Validation
CPV
Integration

5 very hot topics in one session

- Review by Exception (RbE)
- Continuous Manufacturing (CM)
- Advanced Analytics (ML)
- Cell & Gene Therapy (C&G)
- Manual data entry (IPC)
- IoT
- Global Data Infrastructure

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 MERCK

SeeQ®

Spark™
THERAPEUTICS

AZTEC
PROCESS AUTOMATION (P) LTD

Lilly

ROVISYS

Genentech
A Member of the Roche Group

Probably the largest user community for operations data in Life Sciences

770+ members, 260+ organizations

www.pisquare.osisoft.com/groups/life-sciences



Steering Committee

- Biogen
- Lilly
- Genentech
- Roche
- BioMarin
- DRL
- Novo Nordisk



Audit Trail



Kick-off Meeting
PI User Group Audit Trail Tiger Team
November 19th, 2019

Dr. Qi Zhang



Short Introduction of Tiger Team Members



- Secure, computer-generated, time-stamped electronic record that allows for reconstruction of events relating to the creation, modification, or deletion of an electronic record
- Chronology: who, what, when, and why of a record
- Track actions at the record or system level
- CGMP-compliant record-keeping practices prevent data from being lost or obscured
- Deal both with data and metadata ie Process Model and Digital Twin

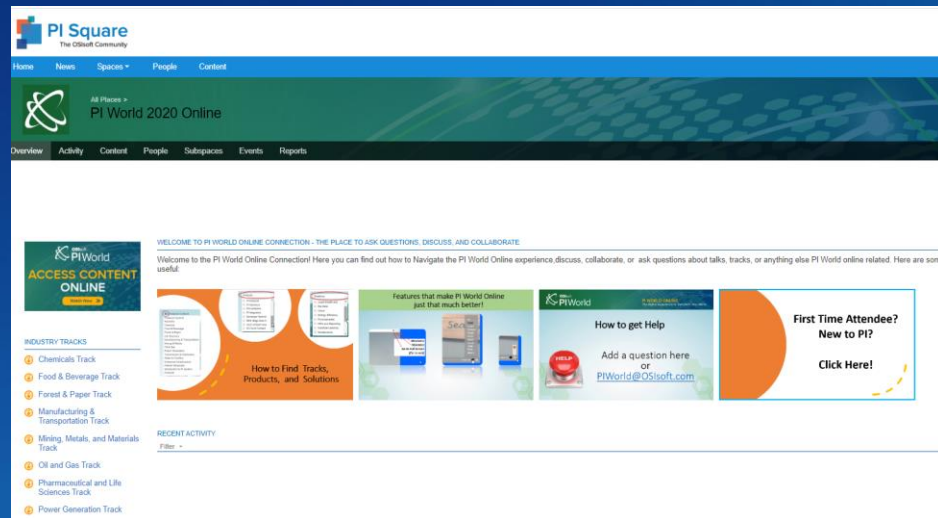
How often should audit trails be reviewed?

FDA recommends that audit trails capturing changes to critical data be reviewed with each record and before final approval of the record.



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- Collaborate with others in your industry
- Discuss PI World Online Content
- Open to everyone
- It's all free

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Join Industry User Groups!



The image displays several overlapping screenshots of the OSISOFT industry user group interfaces. The 'Power Generation' group shows categories like '2019 PGUG Presentations' and '2017 PGUG Presentations'. The 'Life Sciences User Group' shows a list of meeting minutes. The 'Transr' group shows featured content. A central photo shows a panel discussion at a PIWorld event. To the right, a list of industry user groups is provided.

Power Generation

Life Sciences User Group

Transr

INDUSTRY USER GROUPS

- Academic Users Group
- Chemicals User Group
- Data Centers
- Facilities and Energy Manager
- Food and Beverage User Group
- Forest and Paper
- Life Sciences User Group
- Maintenance and Reliability
- Mining, Metals and Materials
- Oil & Gas User Group
- PI System + ArcGIS User Group
- Power Generation
- Transmission and Distribution
- Transportation & Supply Chain
- Water and Wastewater

<https://pisquare.osisoft.com/groups>

Watch “[*How to Make the Most of PI World Online*](#)” to learn more about the platform!

Need help?

Email us at:

PISquare@OSIsoft.com



Stay tuned - More to come!

Post Event Industry Discussions Week of May 18th!

Look on PI Square for logistics
in the coming week!

Questions?



Please remember to...

Fill out the post event survey! It will be emailed to you

