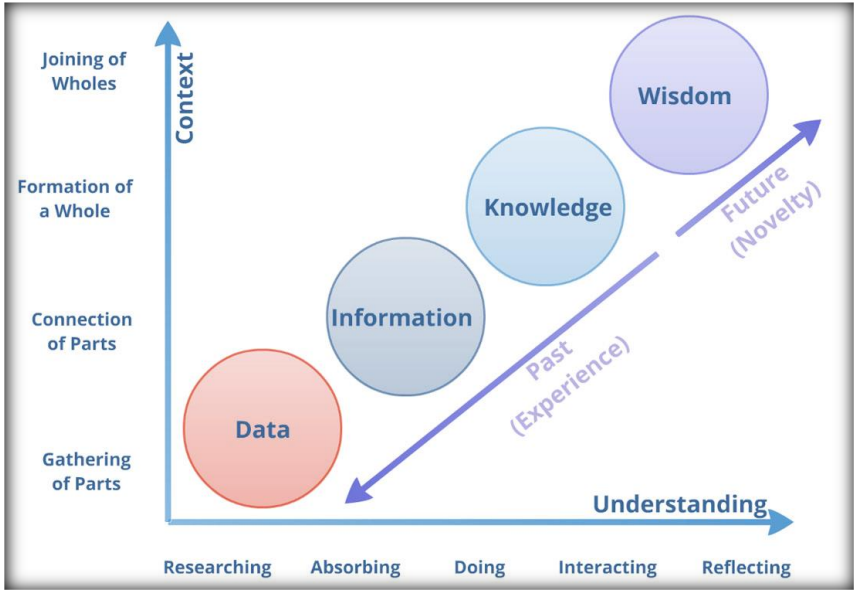
Wrap-Up Life Sciences Track

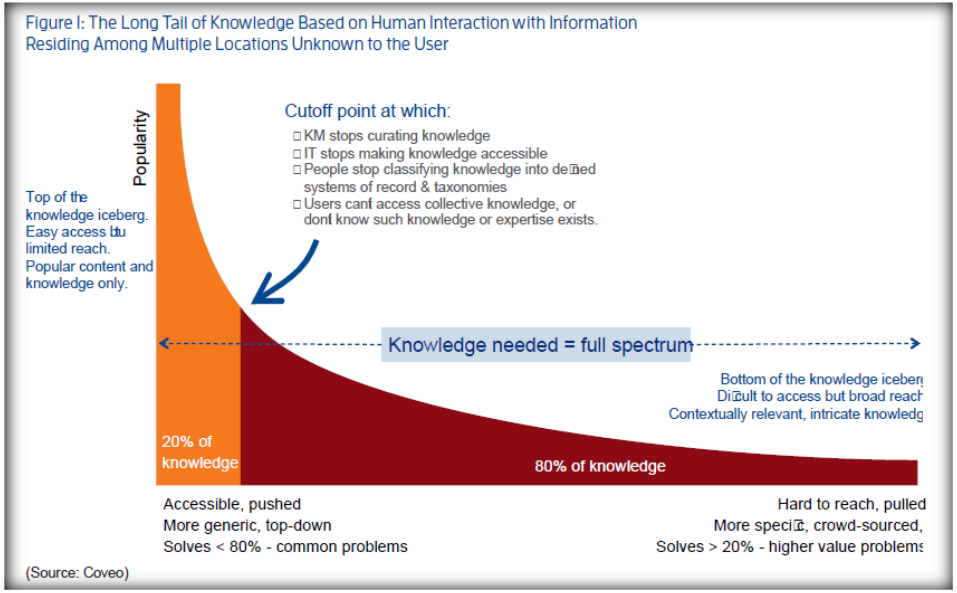
Presented by **Petter Moree**
Industry Principal
Life Sciences, Food & Beverage and Specialty Chemicals

Time	Title	Presenter(s)
9:00 – 9:30	Data Infrastructure and Analytics	Petter Moree – OSIsoft
9:30 – 9:45	**Transfer Time**	
9:45 – 10:15	Monitoring bioreactor cell culture data in real-time with the PI System	Cassandra Murillo, Anthony DeBiase – Regeneron
10:15 – 10:45	**Break**	
10:45 – 11:15	Data Sharing in an OEM Environment	Brian Goldinger, Abel Padilla, Christian Jaeger – Eli Lilly & Process Automation
11:15 – 11:30	**Transfer Time**	
11:30 – 12:15	Data Sharing in a Contract Manufacturing Environment	Brian Goldinger, Abel Padilla, Christian Jaeger – Eli Lilly & Process Automation
12:15 – 2:15	**LUNCH – Grand Ballroom**	
2:15 – 2:45	Pharmaceutical Manufacturing Improvement through leverage of PI Data and Analytical Tools	Robert Forest, Daniel Wasser – Bristol Myers Squibb & Seeq
2:45 – 3:00	**Transfer Time**	
3:00 – 3:30	The Value of the Novartis EA for the San Carlos Site and Novartis Achievements/Goals of the PI System strategy	Serge De Grandpre – Novartis
3:30 – 4:00	**Break**	
4:00 – 4:45	Leveraging the PI System to Build a Biologics Analytics Tool for Laboratory-Scale Bioreactor Data	Sohan Patel – Bristol Myers Squibb
4:45 – 5:15	Wrap-Up	Petter Moree – OSIsoft

Knowledge Management



Source: Russ Ackoff “From Data to Wisdom”, Journal of Applied Systems Analysis, Volume 16, 1989 p 3-9.



Regulatory Views

1.6.1 Knowledge Management

Product and process knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. For example, development activities using scientific approaches provide knowledge for product and process understanding. **Knowledge management is a systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing processes and components.** Sources of knowledge include, but are not limited to prior knowledge (public domain or internally documented); pharmaceutical development studies; technology transfer activities; process validation studies over the product lifecycle; manufacturing experience; innovation; continual improvement; and *change management* activities.

Regulatory views

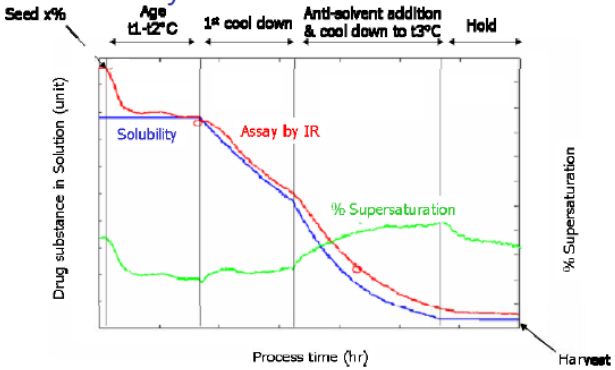
U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Better use of data
Increased transparency
Increased flexibility

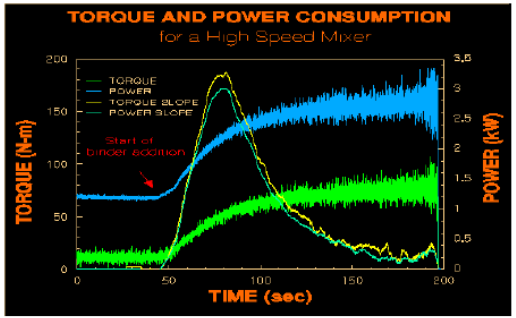
ICHQ8-Q12

Process Signatures

Crystallization



Wet Granulation



http://www.mcc-online.com/granulation.htm

- Many batch processes are path dependent
  - Arriving at the same endpoint does not assure the same quality product
  - Often important physical or chemical attributes are not measured routinely but can affect downstream product performance

FDA References on analytics

U.S. Food and Drug Administration
Protecting and Promoting Public Health
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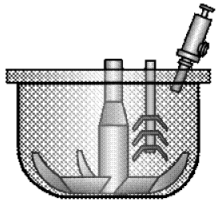
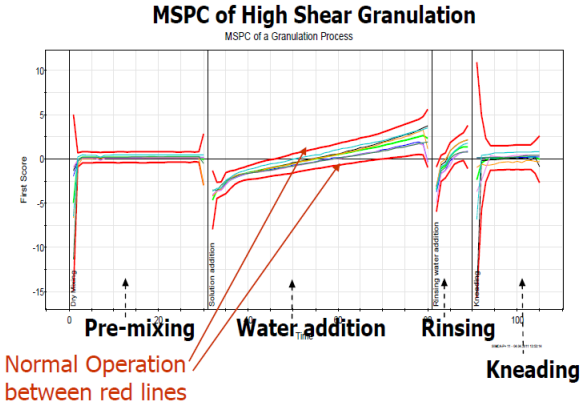
Multivariate Statistical Process Control Example



High Shear
Wet Granulator



- MSPC flags atypical or previously unseen operation
- Outliers do not mean a failed batch but trigger investigation
- Growing examples of "saved" batches due to MSPC

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U.S. Food and Drug Administration
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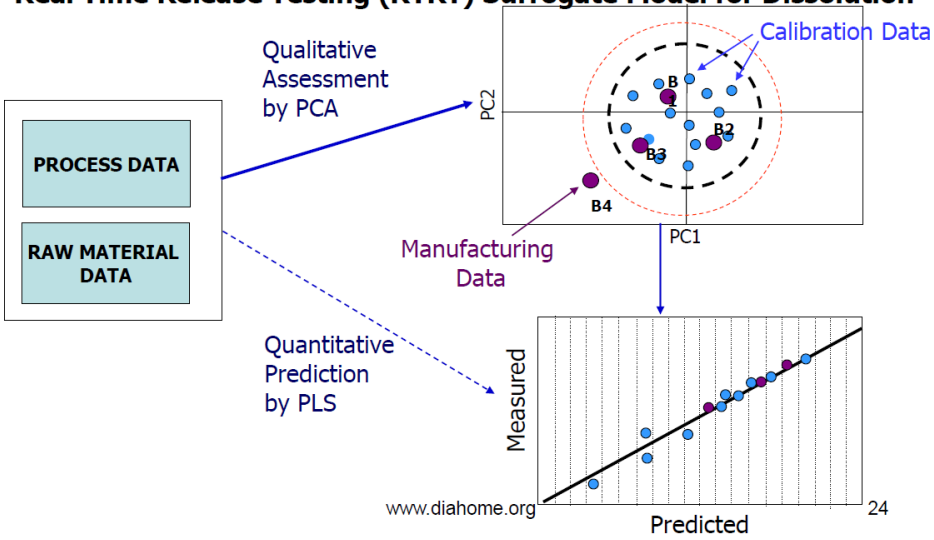
Multivariate Model for Predicting Dissolution

Real Time Release Testing (RTRT) Surrogate Model for Dissolution



www.diahome.org

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FDA view: Model impact and validation

These models are of ML types using for example projection methods such as PCA for summary and PLS for regression/prediction

Considerations for Submission of Models

- **Level of detail in submission should depend on the importance of the model to the overall control strategy**
- **Low Impact Model** (e.g., Models for development)
  - General discussion of how model was used to make decisions during process development
- **Medium Impact Model** (e.g., Design space models)
  - More detailed information about model building, summary of results and statistical analysis
  - Discussion of how the model fits into the control strategy
- **High Impact Model** (e.g., RTRT models)
  - Full description of data collection, pretreatment and analysis
  - Justification of model building approach
  - Statistical summary of results
  - Verification using data external to calibration set
  - Discussion of approaches for model maintenance and update

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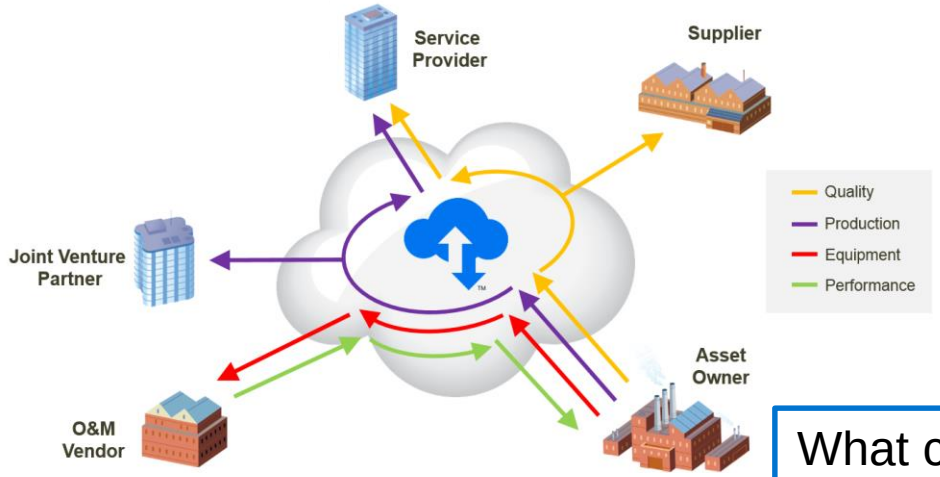
The Ecosystem - Data Exchange is needed in the Pharma Organizations of today



Equipment vendors
Service Partners
- CMO/CDMO
- Analytics
- Integration

Material providers

What controls do **YOU** have over your data at or from your suppliers so that **FDA can rely on your data?**

CMO & CDMO - Data Integrity and Contract Organizations

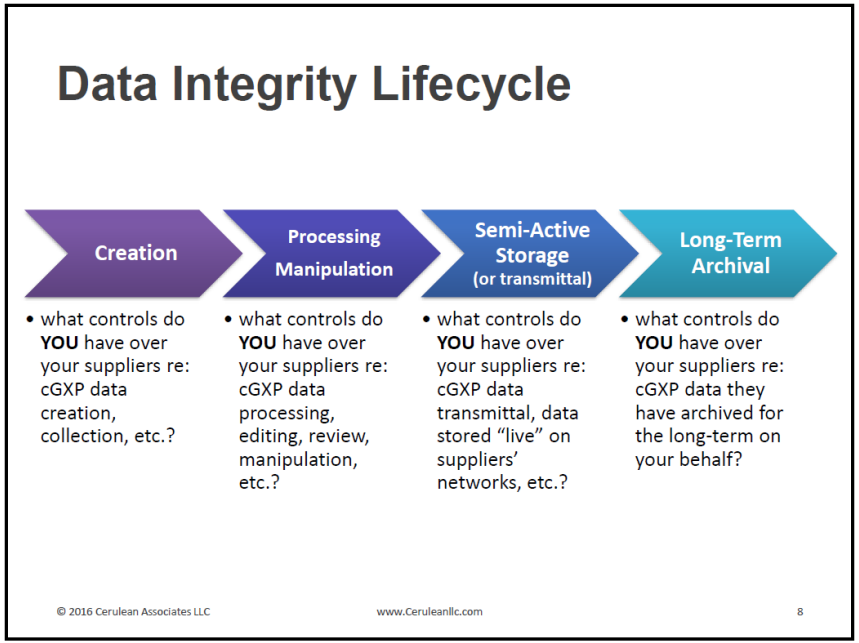
Carmelo Rosa, Director of FDA OMPQ's (Office of Manufacturing & Product Quality), recently acknowledged that "*Data integrity issues have always existed!",* but now FDA is doing more to uncover the evidence of such problems.

Drug makers should not look to contract manufacturers to reduce their responsibility for data accuracy and reliability, Some biopharma companies regard contract testing and production operations as one way to alleviate their involvement in inspections and dealings with regulatory authorities.

Rosa emphasized that the licensed manufacturer remains responsible for products meeting all quality standards and noted that FDA and other authorities are looking closely at all facilities, including CMOs.

Although a Global issue, many of the most egregious data integrity transgressions have surfaced at Indian API & finished product manufacturing facilities.

Data Integrity issues are a Global problem



Source: **John Avellanet – CMO Conference 2016, New Brunswick, www.ceruleanllc.com**

Service vendors and partners - IIoT Values

Customer Experience

- New Digital Services
- New Business Models
- New Revenue Streams

Innovation

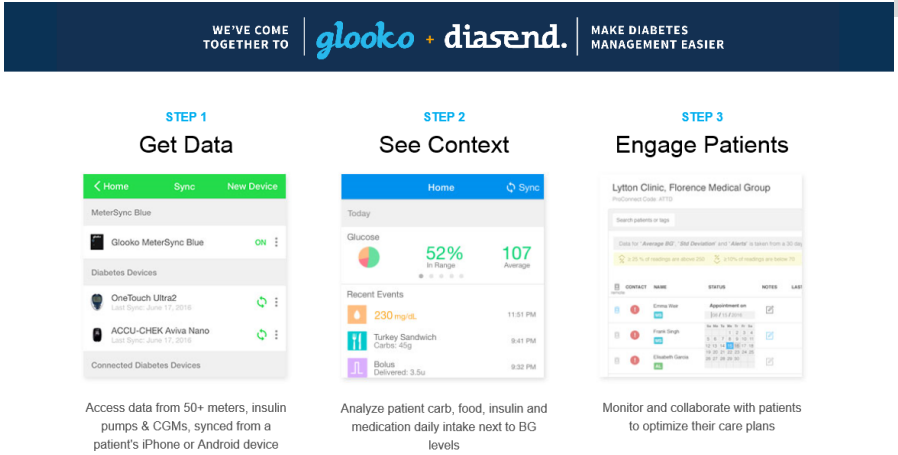
- Insight in Customer Usage
- Product Development
- Time to Market

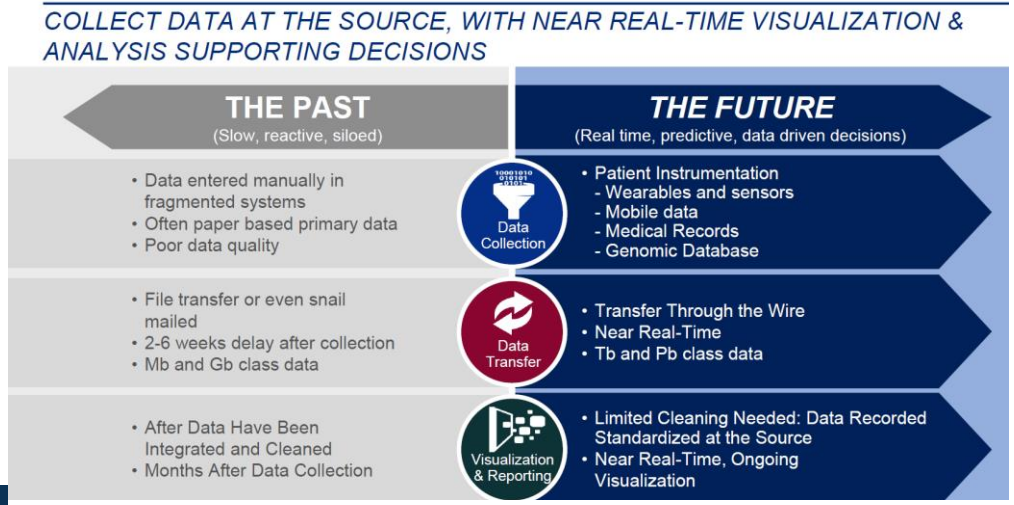
Efficiency

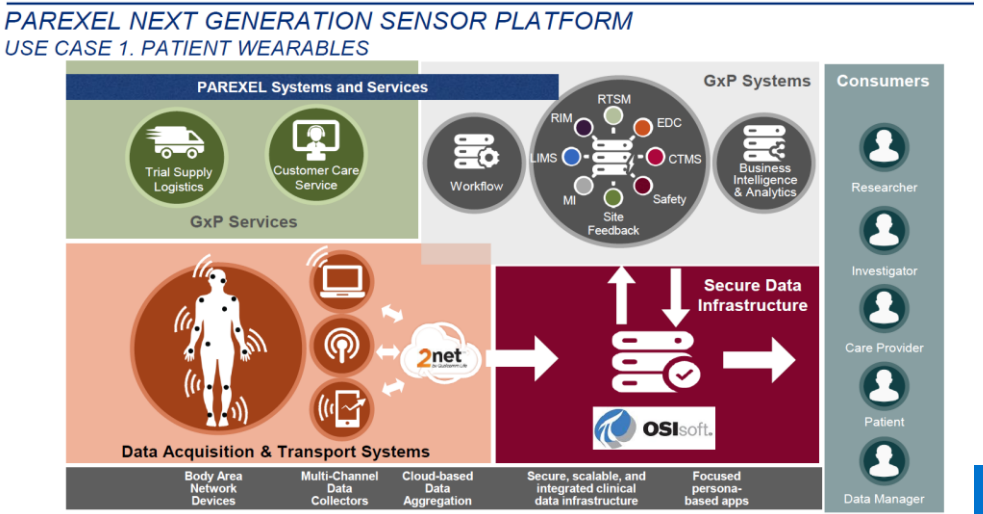
- Remote Monitoring
- Predictive Maintenance
- Optimized Usage/Routing

Communities

- Customer interaction
- CRO Service / CMO
- Personalized Medicine







Data Collection from Devices

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
Shaping the future of surgery

- High value medical assets at customer sites
  - Asset health monitoring
  - On-site support services
- Example drivers:
  - Deliver a value-added service to healthcare facilities
  - Minimize unplanned downtime

Challenges

- Variety of devices
  - Physical form factor
  - Data types
- Thousands to millions of individual connections
- Data flow is intermittent
- Variable network routes
- Diverse data aggregation & processing strategies

Cross Company Data Collection

ELEMENT ANALYTICS™

- Builds predictive maintenance models for rotating equipment as a service
- Uses existing PI System data
  - Extracts data across OT/Cloud boundaries
- Example customer applications:
  - Compressor profiling / early warning
  - Submersible pump failure
  - Wind turbine profiling / maintenance

Challenges

- Separately collect & combine:
  - Process Control Network data
  - Device data delivered via:
    - WiFi
    - Cellular Data
    - Separate IT controlled network
- Store and align data for use in user-facing services

Contact Information

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Questions

Please wait for the **microphone** before asking your questions

State your **name & company**

Please remember to…

Complete the Online Survey for this session

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감사합니다

谢谢

Danke

Merci

Gracias

Thank You

ありがとう

Спасибо

Obrigado