How CDMOs Can Leverage their Most Important Asset: Data

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Agenda

Sartorius Data Analytics Overview
Leveraging Data to Overcome Outsourcing Challenges

Faster and More Reliable Operations: A FUJIFILM Diosynth Biotechnologies’ Case Study

OSI and Sartorius – Partners for CDMO Success
The Evolution of Umetrics® - Born into Data Analytics

1987
Umetrics founded in 1987 by Professor Svante Wold, in Umeå, Sweden

1990s
MODDE® SIMCA® desktop versions introduced

2000
Introduction of first Umetrics real-time process monitoring solutions

2006
First biotech product approval based on QbD principals

2012
SIMCA®-online introduced to market

2017
Sartorius acquires Umetrics®

2019
Sartorius DA Corporate Research Group Established & New HQ opens in Umeå

2020
Release of new analytics platform Umetrics® Studio
## The Umetrics® Suite at Work

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<tr>
<th>Research &amp; Development</th>
<th>Pilot</th>
<th>Manufacturing</th>
<th>Data</th>
<th>Software</th>
<th>Infrastructure</th>
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<tr>
<td><strong>Design of Experiments MODDE®</strong></td>
<td><strong>Multivariate Data Analysis SIMCA®</strong></td>
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<td>Web interface</td>
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<td><strong>Active Dashboard</strong></td>
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<td><strong>Embedded Multivariate Data Analysis SIMCA® -Q</strong></td>
<td><strong>Embedded Design of Experiments MODDE® -Q</strong></td>
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<td><strong>Generating New</strong></td>
<td><strong>Connected GUI available</strong></td>
<td>On-prem. Windows</td>
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### Early Process Development
Lead discovery & optimization | Pre-clinical studies

### Late Process Development
Clinical phase I & I & III production | Commercial production
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Paradigm Shift in the Degree of Outsourcing

1. Growing capabilities of contract organizations attract both big and small biopharma companies
2. Increasing global demand for biologics and biosimilars – particularly in pandemic situations
3. High-costs of establishing in-house facilities and expertise
4. Lack of expertise in development of biologics
5. Growing demand for novel biologics, like ADCs, bispecific antibodies, cell and gene therapies
6. Entry of numerous small and startups that have limited capacities

Clients often stand to lose a significant amount of control and visibility over their processes.

Outsourcing relationships benefit from aligning CDMO expertise with client needs.

Quality has superseded cost savings as the top criterion when companies choose their CDMO partner.

Clients are required to divulge considerable amounts of confidential data.

Data Will Play a Central Role at the Modern CDMO in Addressing These Challenges

- Increased Process Visibility
- Quick Reaction Time
- Enhanced Quality Assurance
- Transparent Data Transfer
- Ensuring IP Integrity

Process Development

Commercial Manufacturing
Modern CDMOs Leverage Advanced Data Services to Achieve Growth

In order to keep up with the increasing reliance from the industry and to stand out from the growing competition, CDMOs are specializing in a number of advanced services to provide greater agility.¹

Services which put a greater importance on:

- Integration and Collaboration for Accelerated Delivery
- Flexibility and Agility for Efficient Operations
- Technological Innovation
- Adapting to a Changing Industry

Growth

Profitability

Trust
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FUJIFILM Diosynth Biotechnologies

- **Who:** FUJIFILM Diosynth Biotechnologies is a leading global CDMO

- **What:** Specializing in cell culture, microbial fermentation and gene therapies with world class cGMP manufacturing facilities.

- **Where:**
  - College Station, Texas, USA
  - Hillerød, Denmark
  - Research Triangle Park, North Carolina, USA
  - Teesside, UK
Faster and More Reliable Operations: A FUJIFILM Diosynth Biotechnologies’ Case Study

**Challenge**

Being able to review and verify process performance is a key step in biopharmaceutical manufacturing. However, traditional chromatography review, like visually reviewing elution peaks, was a *time-consuming, error prone, and paper-intensive* process.

**Solution**

Paring Sartorius Data Analytics tools with OSIsoft PI technology FUJIFILM Diosynth Biotechnologies developed a new digital chromatogram dashboard for enhanced chromatography review.

**Benefits**

- **Shorter** review times, resource expenditure *optimized* tenfold, paper footprint *reduced* by ~10,000 sheets/year, *on demand* data accessibility, and *increased partner trust* and collaboration opportunities.
Using Data Analytics to Overcome Chromatography Review Challenges

SIMCA®-online can detect small deviations in peak shapes before traditional methods can. SIMCA®-online is used to:

• Monitor cycle-to-cycle reproducibility

• Detect column-to-column or batch-to-batch variations

• Identify process failures and other trends before they become problematic
Identify Column-to-Column Variations

**Traditional Univariate Analysis**

Protein A Elution Peaks (UV)

Artefact: excluded from analysis

Significant Variations Difficult to Detect

**Multivariate Analysis**

Column-to-column variations Easy to Detect
Identify Column Malfunctioning

**Traditional Univariate Analysis**

Cycle-to-cycle overlay shows some effect on column 5

**Multivariate Analysis**

Note: Performance decay was found to be related to inadequate cleaning of columns

Column 5 shows deviations from start of run
System Communication: A FUJIFILM Diosynth Biotechnologies’ Case Study

- Historical data stored in the OSI PI system were used as reference batches and to build the digital chromatogram project.
- During production, data ingested from the manufacturing SCADA system to OSI PI system were transmitted to SIMCA®-online through a SimAPI at real-time frequency.
- The visualization dashboard were then made available to operators, quality assurance personnel reviews, and the partner.
Benefits Realized: A FUJIFILM Diosynth Biotechnologies’ Case Study

- **Shorter** review times  →  **Accelerated Delivery**
- Resource expenditure **optimized** tenfold  →  **COGs Optimization**
- Paper footprint **reduced** by ~10,000 sheets/year  →  **Positive Environmental Impact**
- **On demand data** accessibility  →  **Improved Process Traceability**
- **Increased partner trust** and collaboration opportunities  →  **Increased Reliability**

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Why Sartorius and OSIsoft?

**SIMCA®**
- Do you have historical data?
  - A tool for exploring and finding the hidden information in your data.
  - Identifying and distinguish critical from non-critical parameters
  - Powerful learning from historical data
  - Offline root cause investigations
  - Build models for process monitoring and predictions
  - Play with the “What if” functionality

**SIMCA®-online**
- Need added info from Real-Time production?
  - Monitoring the “Golden batch”
  - Real-time root cause investigation
  - Forecast “what will happen”
  - Anticipate process deviations
  - Optimize throughput
  - Stable production advisor

**SIMCA®-Q**
- Want to build your own application?
  - Embedded Multivariate Data Analytics
  - Automate and speed up decision making
  - Make complex tasks routine
  - Reduce the risk of human error
  - Can be used for batch, discrete or continuous data
  - Validation report and documentation available
CDMOs are Putting a Greater Importance on Data and Data Analytics

“Data integrity deficiencies are cited in 65% of all FDA warning letters”¹

Consequently this has put pressure on CDMOs to implement data management systems that provide transparency, preserve customer confidentiality, and meet regulatory guidelines.

CDMOs have realized the additional value opportunity that comes with adopting data management systems along with data analytics tools and have transformed these new technologies into service offerings.

Benefits of Adopting Data Driven Technologies at a CDMO

- Enhanced Process Understanding
- Greater Internal and External Collaboration
- Resource Optimization (Time, COGs)

- Quality & Regulatory Assurance
- Increased Partner Trust
- Maximized Revenue
THANK YOU
Acknowledgements and References

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Want to learn more about the value of Data Analytics at CDMOs?

Don’t miss the upcoming webinar on Nov 12, 4pm – 5pm.

Topic: How Data Analytics can Boost the Bottom Line at a CDMO

With new technologies come new business opportunities. In this webinar Sartorius will present how to data analytics can be used to maximize productivity and profitability at a contract (bio)pharma organization. On top of the more commonly known benefits, like reducing batch variability, data analytics also provides a unique upsell opportunity for CDMOs. By innovating their service offerings, CDMOs can address some of the major challenges their partners face when deciding to outsource their operations, like loss of control or quality management. In this webinar, we will propose a scenario in which a CDMO can double its’ return of investment in just one year! At the end of the day, CDMO’s who choose to innovate their offerings can secure higher value contracts, grow their sales pipelines, and attract long-term strategic partners.

Presenters:
Tiffany McLeod, Market Manager Pharma Biopharma, Sartorius Data Analytics
Tigran Lachinyan, Strategic Marketing Manager, Sartorius BPS