



BioPharma
Product Testing

Implication of new EU GMP ANNEX I:

High-throughput testing of pharmaceutical water

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Speaker

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Eurofins

World Leader in Testing for Life.



Eurofins BioPharma Product Testing

World's largest network of GMP product testing labs



20
countries



8,200
employees



40
laboratories



One stop shop
for R&D
and QC

Subject Matter Expert (SME) Support for Annex I

- Support for Contamination Control Strategy
- Individual Sampling Plans for Process Performance Qualification (PPQ) Projects and Environmental Monitoring
 - Ultra-Pure Water Systems
 - Cleanrooms
 - Cleaning Validation
- Sampling Plan creation and insurance of timely Sampling
- Quarterly and Yearly Trend Report Creation and Review (for Monitoring)
- On-Site Support available
 - Alert and Action Investigation (OOS)
 - Contamination Investigation
 - Trend Investigation
 - Troubleshooting
 - Consulting
- Single Point of Contact as Project Managers
- Time Planning for Overall Project Timelines

Compendial Water Testing - Capability

- As per Eudralex Annex 1 Chapter 6 «Utilities»:
- Risk assessment as part of the CCS, defining the utility system sampling points.
- Continues trend monitoring to ensure system capabilities
- Monitor chemical (e.g. TOC, Endotoxin, conductivity) and microbial parameters (e.g. TAMC) as per defined action and alert limits
- Monitoring parameters given as per EP
 - monograph 0008 for WP
 - monograph 0169 for WFI

Compendial Water Testing - as part of Annex I

Microbiology Non-Sterile Products



- Microbial Limits (TAMC, TYMC, ..)
- Specified Micro-organisms
- Method-Verification
- Growth Promotion
- Efficacy of Antimicrobial Preservation
- Endotoxin

- Organism Identification *

* via Eurofins Partner Site(s)

Compendial Water Testing



- Bioburden
- Endotoxin
- Total Organic Carbon (TOC)
- Conductivity / pH
- Nitrate*

Daily Sample Capacity:

Water: > 300

Surface, Air: > 500

Utilities & Environment



- Qualification Projects
 - Ultra-pure water systems
 - Cleanrooms
 - On-Site Sampling (site specific)
 - Pick-up + Direct Logistics

- Environmental Monitoring
 - Water
 - Surface
 - Air
 - Gas *

Compendial Water Testing - Requirements

EP & USP Requirements for Pharmaceutical Water

Endotoxin EP 2.6.14 / USP <85>
Microbial Count EP / USP <1231>*
Sterility EP 2.6.1 / USP <71>
ID of Microbes EP 2.6.13 / USP <1231>
Conductivity EP 2.2.38 / USP <645>
TOC EP 2.2.44 / USP <643>
Oxid. substances EP 2.5.30
*Appearance EP**
*Nitrate EP**
Aluminium EP 2.4.17
Heavy Metals EP 2.4.8
*Acidity or alkalinity EP**
Calcium EP 2.4.3
Chloride EP 2.4.4
Magnesium EP 2.4.6
Sulfates EP 2.4.13
Ammonium EP 2.4.1
*Residue on evaporation EP**
Invisible Particles EP 2.9.19

Water for Pharmaceutical Use		Microbiological Testing				Physico-chemical Parameters															
Purified Water <i>Aqua purificata</i> EP 0008	in Bulk	X (1)	X		R	X	X (2)	X (2)	X	X	X (1)	O (3)									
	in Container	X (1)	X		R	X	O	X	X	X	X (1)	O (3)	X	X	X	X	X	X	X		
Water for Injection <i>Aqua ad iniectionabile</i> EP 0169	in Bulk	X	X		R	X	X		X	X	X (1)	O (3)									
	Sterile WFI	X		X		X		X	X	X	X (1)	O (3)	X	X	X	X	X	X	X	X	
Purified Water <i>Aqua purificata</i> USP <1231>	in Bulk		X		X	X	X	X = required, mandatory O = optional as old R = recommended													
	Sterile PW			X		X	X	Note: Limits are harmonized across EP and USP (1) only for dialysis applications; (2) EP, one of both tests (3) no longer in EP TOC, Total Organic Carbon ; (4) and test for particulate matter <788> EP*, see monograph for Purified Water (0008) and/or Water for injection (0169) On request, Highly Purified Water according to old EP 1927, and other pharmacopeia													
Water for Injection <i>Aqua ad iniectionabile</i> USP <1231>	in Bulk	X	X		X	X	X														
	Sterile WFI (4)	X		X		X	X														

Bioburden Process Integration: Time is Crucial

- Operational / Physical Process: **24 hours time window for Bioburden**
 - Sampling (optional service)
 - Sample Pick-up and Transport within Switzerland (time point aligned with client)
 - Direct Logistics to Eurofins lab site in Schoenenwerd
 - Same-Day testing initiation (incl. evening)
- IT process integration from client to Eurofins
 - Online-Ordering
 - Customized project configuration
 - Data connection within Eurofins laboratories (as required, e.g. for Microbial ID)
 - Client Data Platform for Results and Raw Data: LabAccess
 - Interface from Eurofins LIMS to client LIMS (LAWS)

Sampling

- Sampling as **optional** on-site Service for Environmental / Utility Monitoring
 - a. Eurofins **BPT** Switzerland AG: microbiology lab technicians
 - a. Closer proximity around Schönenwerd (~ 100 km)
 - b. Monthly / quarterly
 - b. Eurofins Professional Scientific Services (**PSS**):
 - a. Dedicated resources (> 1 year contract)
 - b. FTE model
 - c. Local teams (on-site)
 - c. (Client resources)



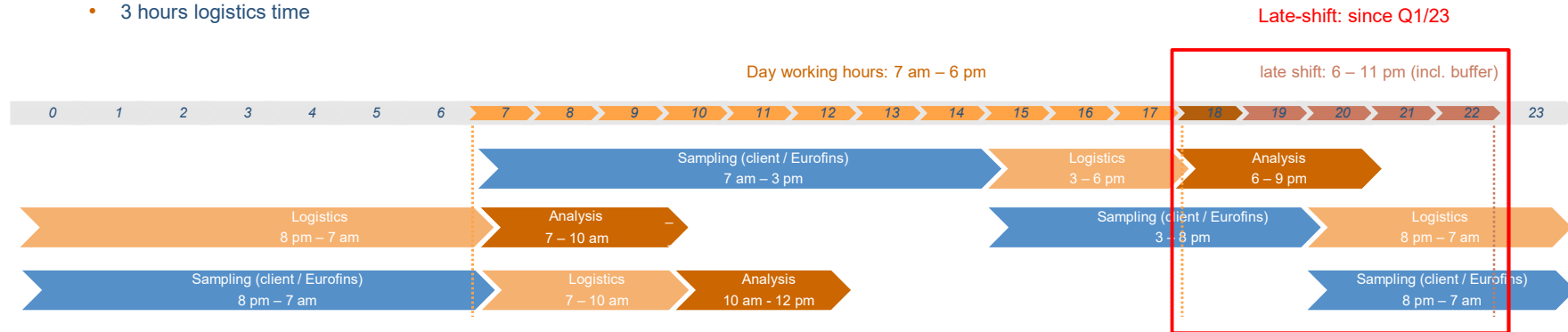
Sample Logistics

- Direct transport to the Eurofins BPT lab in Schoenenwerd
- Long-Range: Service is provided for all areas in Switzerland
- 2-3 x daily (ensures 24 hours time-window for Bioburden)
- Night-Delivery is optional
- Established logistics
 - a. Eurofins Courier
 - b. Qualified Logistics Partners
- Same day analytical process initiation
- Convenience: Shipping Materials are provided by Eurofins
 - Boxes
 - Cooling Kits
 - Data Loggers



Same-Day Analysis / Late Shift

- Maximization of available **laboratory time** for our clients = maximization of potential **sampling time**
- Definition of pick-up times: ensure aligned process within **24-hour** time window
- Process Example:
 - 3-transport-approach (7 am / 2 pm / 8 pm)
 - 3 hours logistics time



Sampling:

- **cut-off times**
- sampling: > 300 samples daily
- electronic order transmission (**online-ordering**: LabAccess)

Logistics:

- **sample pick-up**
- **transfer within Switzerland**
- **no borders/customs!**
- exchange of transport boxes (daily)

Testing:

- **Sample reception confirmation**
- **same day initiation: Bioburden**
- 48 hours initiation: TOC, Endotoxin
- Daily lab **capacity > 300 samples**

Microbial ID: MALDI / Sequencing

- Close cooperation with **Centers of Excellence** within Eurofins
 - Close technical collaboration
 - **IT-connection**: electronic data exchange with Eurofins Microbiology Laboratories
- Phenotypic identification: MALDI-TOF
- Genotypic identification
- Unilocus Comparative Sequencing (ULSA)
- Bacteria: 16S rRNA Gene **Long Sequencing**
 - 1'350 base pairs (taxonomic reference)
 - Amplification by PCR
 - **1st world database** with **more than 9'300 references**
 - More reliable: **more discriminating** than partial sequencing
- Fungi : 25S rRNA Gene or ITS1/ITS2 Partial Sequencing
- Multilocus Comparative Sequencing (MLSA) :
 - Reconciliation of results / autocontrol

IT Process Integration: eLIMS-BPT

- Exclusive Eurofins **Proprietary Software**
 - Key **harmonization** driver for Eurofins BPT
 - CoA, laboratory investigations, sample tracking, equipment & reagents management, etc.
- Development:
 - Designed and developed for pharmaceutical industry and **GMP** requirements (2 years project ; 40+ FTE **development team**)
 - **New functionality modules** and improvements released every 2-3 months
- Compliance:
 - FDA 21 CFR Part 11 compliant
 - Fully validated
- **Connectivity**
 - Online Ordering
 - Customized project configuration (Analytical Service Templates)
 - LabAccess (results)
 - Data connections across Eurofins BPT Sites
 - Quotations

Labaccess: On-line Ordering & Data Access LIMS to LIMS Data Transfer



Your needs		Improves
On-line Ordering	<ul style="list-style-type: none"> • since 2021, still being deployed • quick, easy & transparent order submissions • from an existing or new PO • register sample & select tests 	<ul style="list-style-type: none"> • Turn Around Time (TAT) – laboratory is prepared in advance of sample arrival • Quality – manual transcription and decision making is significantly reduced • Information Access - historical views
On-line data access	<ul style="list-style-type: none"> • test results, CoA • PDF images of all raw data • financial information (invoices, quotes, POs) • stability information: protocols/ studies/ calendar • quality exceptions • historical views & trends 	
LAWS LabAccess Web Services	<ul style="list-style-type: none"> • LAWS is a set of restful services for data transfer • From eLIMS BPT (Eurofins LIMS) to your LIMS • Allows for 24/7 access to any reported data, in real time 	<ul style="list-style-type: none"> • Speed of data processing

Summary: Competitive Water Testing Service Solutions

- Sampling
- Logistics:
 - Local proximity
 - Daily logistics
 - Same-Day Analysis
- Analytics:
 - Compendial Methods
 - Quality + Precision: GMP
- IT Process Efficiency:
 - Scalable Routine Processes
 - Strong IT Solutions
 - eLIMS-BPT
 - Online-Ordering
 - LabAccess
 - Fast TAT: at technical limit
 - High Capacity



Questions? Get In Touch!

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Thank you



Get in touch

We value our client's time and therefore serve you from our closest-by location.

For a quick response, contact our local experts directly.