# FLEX EP for Automated Eluent Preparation under GMP

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RAYA 2023 Finalist Event

# Agenda

1. Chemspeed Technologies | Compliant Solutions
2. Introduction to FLEX EP
3. Evaluation Criteria
4. Why FLEX EP should get the Audience Award today ☺

The Chemistry Hotspot in the Middle of Europe

# Near Basel


Swiss Precision

25 Years Experience

Globally Operating

70% Chemists & Engineers

# Chemspeed technologies | Compliant Solutions

Columbus, OH Office, US

Liverpool Office, UK

Essen Office, DE

**Europe / America / Africa:**

Nova Analítica

Separation Scientific SA

Labtim

Alenium Scientific S.L

**Asia and Australia:**

AMR Inc

Yamamoto Trading

Bargal

CM Corp

Inkarp

ITS

Nikyang

Thermo Fisher

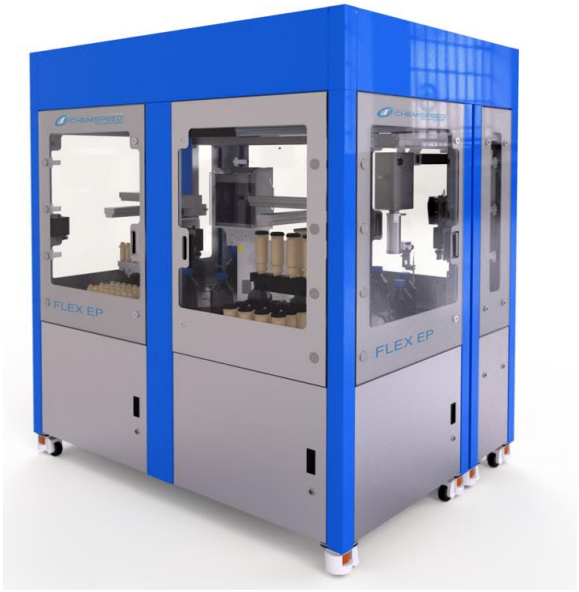
North Brunswick, NJ Office, US

**Füllinsdorf HQ, CH**

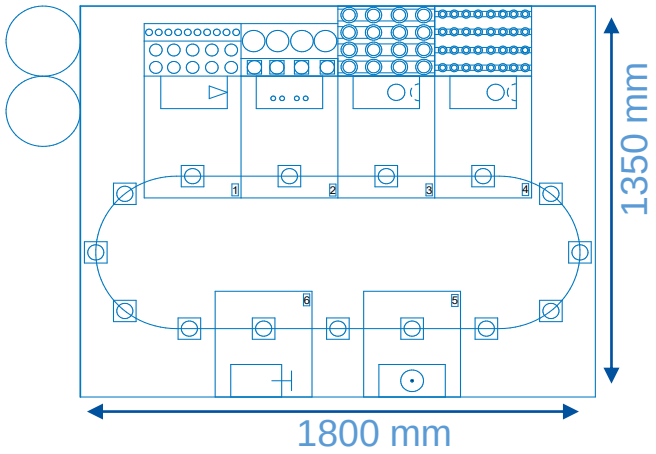
Shenzen joined office, PRC

# FLEX EP Compliance-Ready Automated Workstation

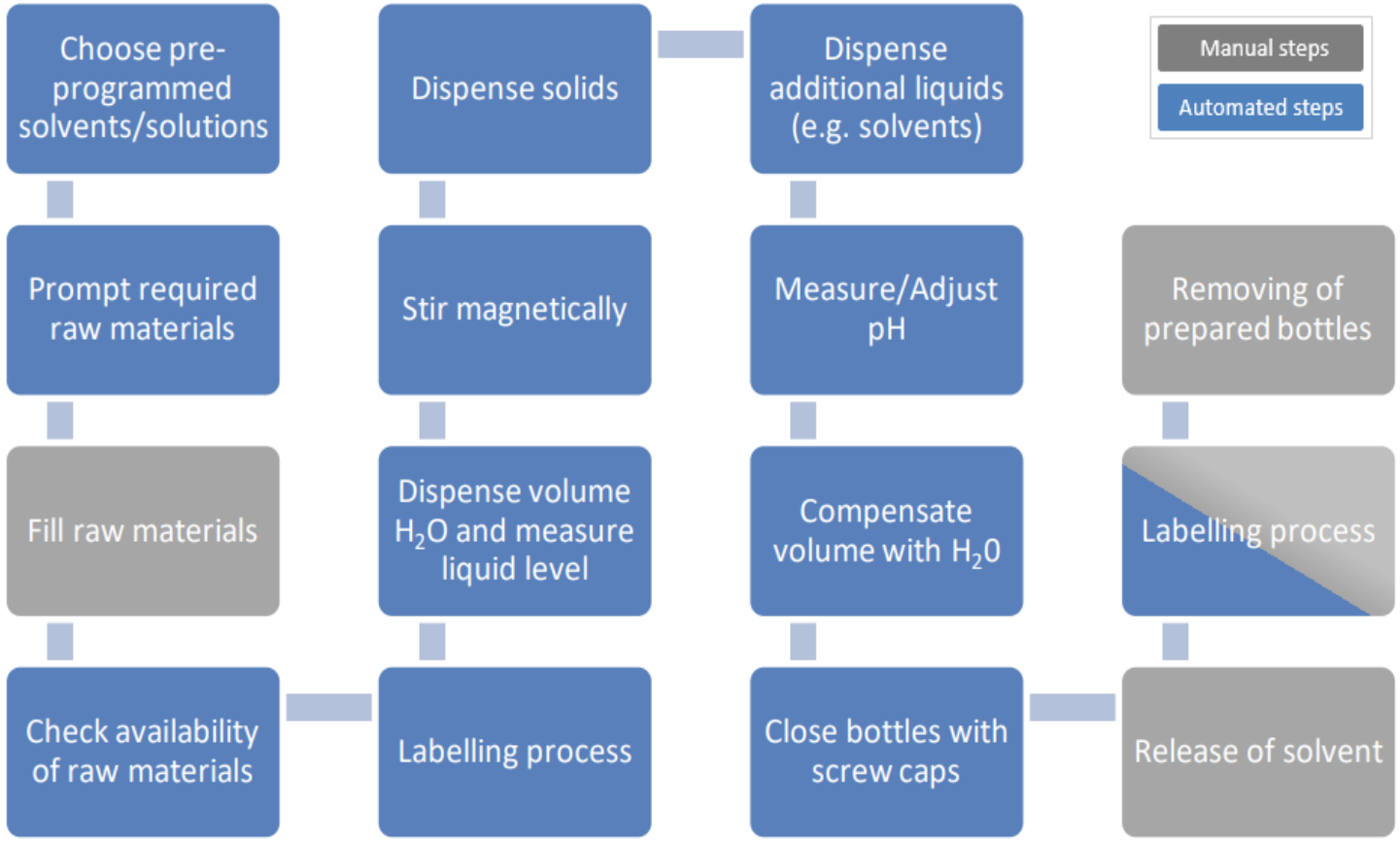
## Fully automated workstation for the autonomous eluent preparation




- Eluents are prepared directly into 0.5, 1, 2 L Schott bottles.
- Throughput of up to 120 L/day.
- Fully digital documentation and audit trail.
- Software enables full compliance with FDA 21 CFR part 11.
- Fast qualification process (GAMP 5 category 4 system).
- Reduced human error in everyday operations and method transfers.



# FLEX EP Workflow Overview



# FLEX EP Platform Overview



https://nextcloud.chemspeed.com/s/Y3DaoWZ6Xg9iFLE

# Evaluation Criteria - Area of Application

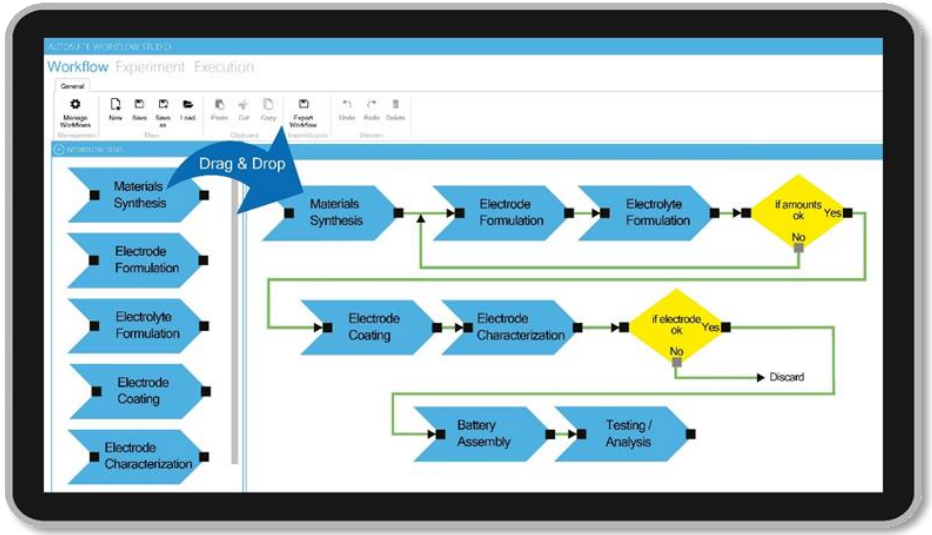
## FLEX EP can be leveraged throughout the entire analytical method life cycle:

- From RnD labs and method development to QC routine application, where the same analytical methods can be accessed and used (once approved and released).
- Between different sites: removing the risk of individual recipe interpretations.
- From Pharmaceutical company to 3rd party contractors and vice versa (C(D)MOs, CROs) with seamless method transfers.

# Evaluation Criteria - Attractiveness

## FLEX EP offers Improved Process Quality, Efficiency, 24/7 availability

- Seamless integration throughout entire analytical method life cycle.
- Software enables full compliance with FDAs 21 CFR part 11,
- Documentation and Audit trail.
- Reproducibility and robustness in workflow execution.
- Risk reduction due to technology.
- Centralized and accessible.
- Business continuity with ArkSuite Sofia digitalization tool.



# Evaluation Criteria – Easy Integration and Flexibility

## Easy Integration and Futureproofing through upgrade options

- FLEX EP is designed as GAMP 5 Category 4 system providing us easier and faster qualification.
- We do provide some customization to FLEX EP:
  - Connection to direct solvent lines or large solvent tanks.
  - Connection to direct waste lines, or external waste tank.
  - Interface to LIMS.
- It is possible to adapt the workflow with additional extensions, for example:
  - Automated eluent bottle loading/unloading.
  - Automated filtration of prepared solution.
  - Conductivity measurement.
  - Integration with mobile robots to transport prepared eluent to either storage or HPLC facility.

# Evaluation Criteria - Cost effectiveness & ROI

## FLEX EP simplified ROI calculations:

| Yearly cost per FTE | 150 kEUR | 120 kEUR | 90 kEUR | 60 kEUR |
|---|---|---|---|---|
| Yearly eluent consumption, L | Breakeven Time, years | | | |
| 2000 | > 5 | > 5 | > 5 | > 5 |
| 3000 | 4.9 | > 5 | > 5 | > 5 |
| 4000 | 3.1 | 4.2 | > 5 | > 5 |
| 5000 | 2.3 | 3.0 | 4.4 | > 5 |
| 6000 | 1.8 | 2.4 | 3.4 | > 5 |
| 7000 | 1.5 | 2.0 | 2.8 | 4.7 |
| 8000 | 1.3 | 1.7 | 2.3 | 3.8 |
| 9000 | 1.1 | 1.4 | 2.0 | 3.3 |
| 10000 | 1.0 | 1.3 | 1.8 | 2.8 |
| 11000 | 0.9 | 1.1 | 1.6 | 2.5 |
| 12000 | 0.8 | 1.0 | 1.4 | 2.3 |
| 13000 | 0.7 | 0.9 | 1.3 | 2.0 |
| 14000 | 0.7 | 0.9 | 1.2 | 1.9 |
| 15000 | 0.6 | 0.8 | 1.1 | 1.7 |

# Why FLEX EP should get the Audience Award today ☺

1. Routine task automated.
   a. Eluent prep is repetitive, resource consuming and not very exciting, which leads to high workforce turnover.
   b. Last point you want to check when there is an error in your HPLC analysis.
   c. Challenging to automate (handling organic, aqueous, acid/base and solid materials).
2. FLEX EP is 2nd generation, designed for serial production.
   a. GAMP 5 Category 4 system for faster qualification.
   b. Attractive ROI with breakeven in less than 3 years.
3. Business continuity with ArkSuite Sofia Software (AR).
   a. Assuring 24/7 accessibility.

# Thank you for your time!

**Our envisioned Future of Pharmaceutical R&D and QC**