31. Swiss Cleanroom Community Event



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# Innomedica Case Study: A revolutionary concept for small batch-production of biopharmaceuticals inside a closed isolator

BTS

# The Challenge

## The Story

- A startup biotech company
- With their newly developed liposomal medicine (cytotoxic)
- Facing the critical task of filling for use in clinical trials
  (1 batch of 600 vials)

## The Standard Approach

- Outsource the sterile filling process to a CMO
  (Contract Manufacturing Organization)

## The Problem

- High costs: €400k + for feasibility study only (no production)
- Too slow: Long lead times (6-8 months)
- Complexity: Technology transfer to external partner
- Cytotoxic risks: Hesitance from CMO to handle these compounds



# The Solution

## New Strategy

- Bring the sterile filling capability in-house
- Develop small size and less expensive filling machines
- Find innovators with affordable isolators

## The Partner

- Market Research found **Ecolab** and its Bioquell Qube™ Isolators
- Modular concept (one to three chambers), material transfer hatches
- Rapid 6-log Bio-Decontamination
- Flexibility to fill small batches to large scale production

## The Cost-Effective and Space-Saving Solution

- Sterile filling production line
- BTS semi automatic and fully automatic filling machines
- Bioquell Qube Isolator system



Fully Automated Vial Filling in a Bioquell Qube isolator

# The Hidden Costs of Manual Filling – And Why We Left It Behind

| Criteria | Manual Filling ( The Risk) |
|---|---|
| ⏱️ **Throughput** | Severely limited – depends on operator speed and daily stamina |
| 👷 **Labor** | High manpower demand – ties up skilled staff in repetitive tasks |
| 📋 **Traceability** | Not feasible – difficult to document and nearly impossible to validate |
| ⚠️ **Contamination** | High risk – open vials and constant human intervention |
| 📈 **Scalability** | Dead end – not viable for commercial batch sizes |
| 💰 **Running Costs** | Cleanroom maintenance, energy, gowning, environmental monitoring results in high costs |



# Fully Automated Filling Systems – Efficient, but Inflexible

✅ **Good for:** High-volume mass production after market launch.
❌ **NOT suitable for:**

| Criteria | Fully automated Filling ( The Risk) |
|---|---|
| R&D and Clinical Trials | No flexibility for changing batch sizes or formulations |
| Small-to-Medium Batches | Not economical; only profitable at full capacity |
| Limited cleanroom space | Requires an enormous equipment footprint |
| Frequent changeovers | Time-consuming and costly to reconfigure |

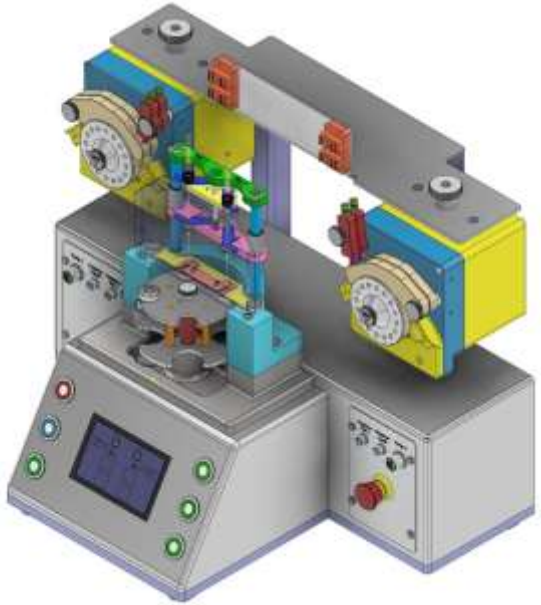




# BTS Filling solutions – built for GMP from Day One

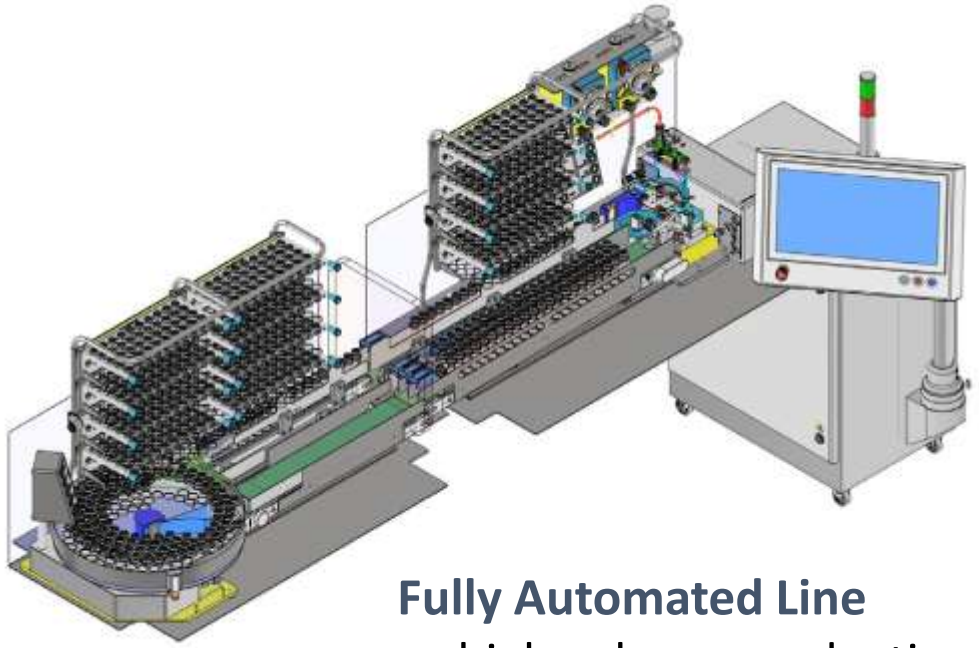
**Development in Cooperation with a Swiss Pharma Startup Company**
**Since 2020**, we have been engineering advanced filling systems

Current Portfolio offers **two GMP-compliant systems**, tailored to progress of product lifescycle



**Semi-Automated Line**

- maximum flexibility
- for R&D, clinical trials, and small batches



**Fully Automated Line**

- high volume production
- for commercial launch

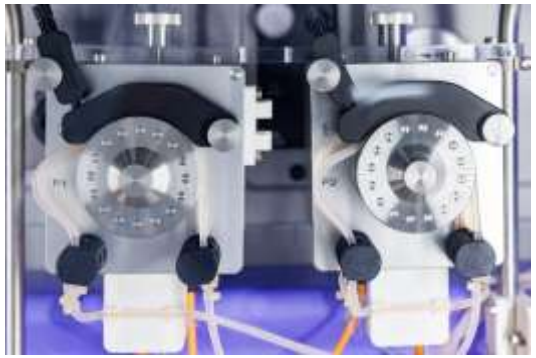
# The Smarter Alternative – Scalable Technology

**BTS Key Technology Success Factors**

| Open Vial filling | Closed Vial filling | Integrated Pumps | Double Speed, Two Vials at a Time |
|---|---|---|---|







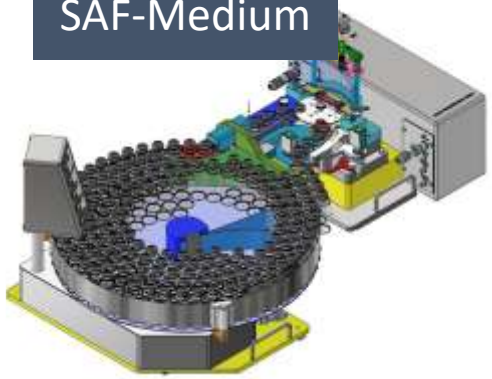


# Capacites: Filling automation by BTS

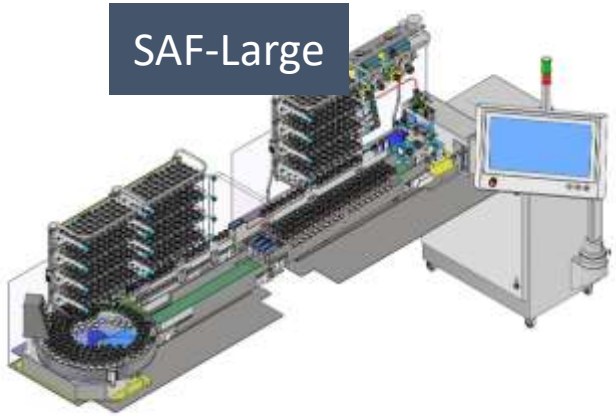
SAF-Small



SAF-Medium



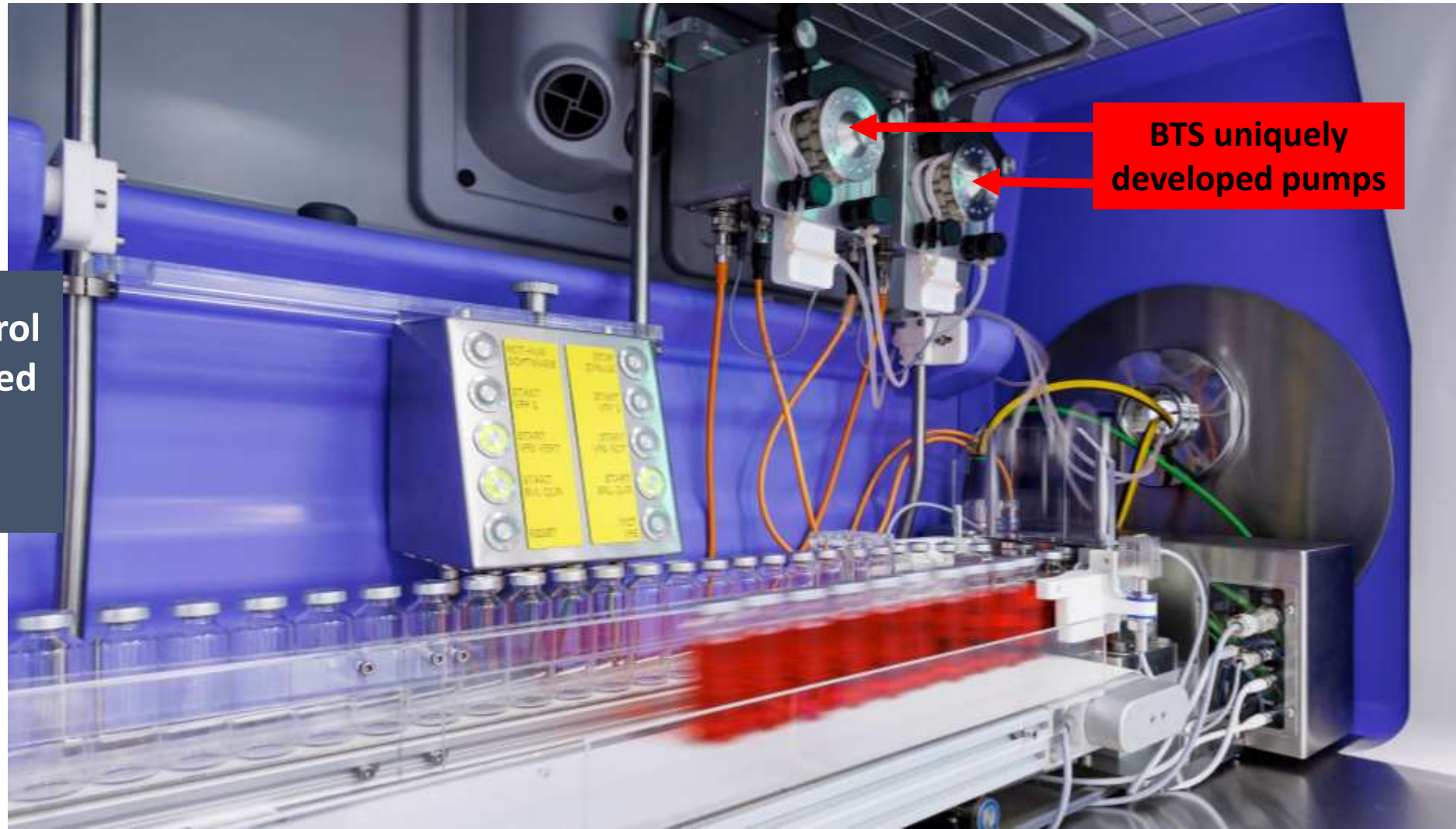
SAF-Large



| Loading capacity | 1 – 2 vials | ~ 150 – 200 Vials | 600 Vials (30 mL) |
|---|---|---|---|
| **Filling speed** | **200 vials/h (30 ml)** | **180 vials/h** | **200 vials/h (30 ml)** |
| High Precision dosage Pump | Yes | Yes | Yes |
| Operation | Manually, continuous | Fully automated | Fully automated |
| Work area needed | 510 mm x 375 mm | 200 mm x 600 mm | 2x 700 x 350 mm |
| Control panel | HMI | HMI | HMI |
| Isolator Chambers Required | Single | Single | Double |

# Automation: Speed controllable perisaltic filling pumbs

Precise dosage control with adjustable speed for different formulations



# Automation: Door with lockable acess betwenn zones



**Secure, controlled access maintaining GMP grade…**

# BTS Automatic Filling in the Bioquell Qube Isolator

Benefits of the Bioquell Qube

- Cost-effective solution due to unique polypropylene construction
- Installed and Validated in **16 weeks**
- Rapid bio-decontamination cycles (c.30 mins)
- EU GMP Annex 1 and Swiss Medic Certified




ECOLAB | bioquell An Ecolab Solution

# GMP Documtation Support

## Complete GMP documentation

- from SOP procedures to qualification
- System validation
- regulatory compliance
- audit-readyness

## GMP Package includes

- Material certificates for regulatory compliance
- URS: User Requirement Specifications
- DQ: Design conforms to specifications
- IQ: Installation is correct and complete
- OQ: System operates as intended
- PQ: Customer product specific application is functional
- SOPs for the robot use
- Logbook template to track robot use and maintenance
- Customer support with Media Fill validation
- Operator training by BTS personnel on customer site


IQ/OQ/PQ – Semi-automated closed-vial filling system

5. SYSTEM DESCRIPTION

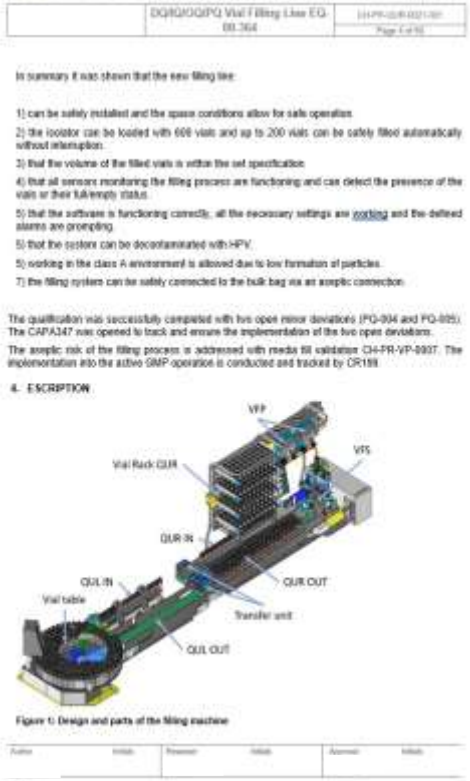


Figure 1: Design and parts of the filling machine

# Contact us –
# Let's Discuss Your Filling Needs

BTS Business Technology & Services
Software and Automation

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**-> From R&D to commercial production, we deliver the right filling solution for every stage of your product lifecycle**