



Aseptic Filling Workcells

Gloveless Robotic Isolators for Aseptic Filling

Brendan Bradley- Vanrx Pharmasystems
Brent Lieffers- Singota Solutions



Topics for today

DRIVERS FOR REDESIGNING ASEPTIC FILLING

AUTOMATION STRATEGIES AND KEY TECHNOLOGIES

**CUSTOMER CASE STUDY:
SINGOTA SOLUTIONS**



About Vanrx

Biologics
manufacturing
experts



Redesign aseptic
filling



Targeted drug
products with
smaller patient
populations



Founded in
Vancouver,
Canada

Current Aseptic Filling Challenges



Multiple dosage formats



Ease of use

	PRE CLINICAL	PHASE 1	PHASE 2	PHASE 3
<p>► NuThrax™ (AV7909)</p> <p>Anthrax Vaccine Candidate (Anthrax Vaccine Adsorbed with CPG 7909 Adjuvant) *Phase 3 Study: First subject enrollment targeted for 2019</p>				2019*
<p>► FLU-IGIV</p> <p>Seasonal Influenza Therapeutic Candidate Hyperimmune Platform **Phase 3 Study: First subject enrollment targeted for 2019</p>				2019**
<p>► VLA1601</p> <p>Zika Virus Candidate Injectable Purified, Inactivated Zika Virus Vaccine</p>				
<p>► ZIKV-IG</p> <p>Zika Therapeutic Candidate Hyperimmune Platform **Phase 1 Study: First subject enrollment targeted for 2018</p>				
<p>► UNI-FLU</p> <p>Universal Influenza Vaccine Candidate Injectable Nanoparticle Universal Influenza Vaccine</p>				
<p>► EBX-205</p>				

Speed to market and *in market*

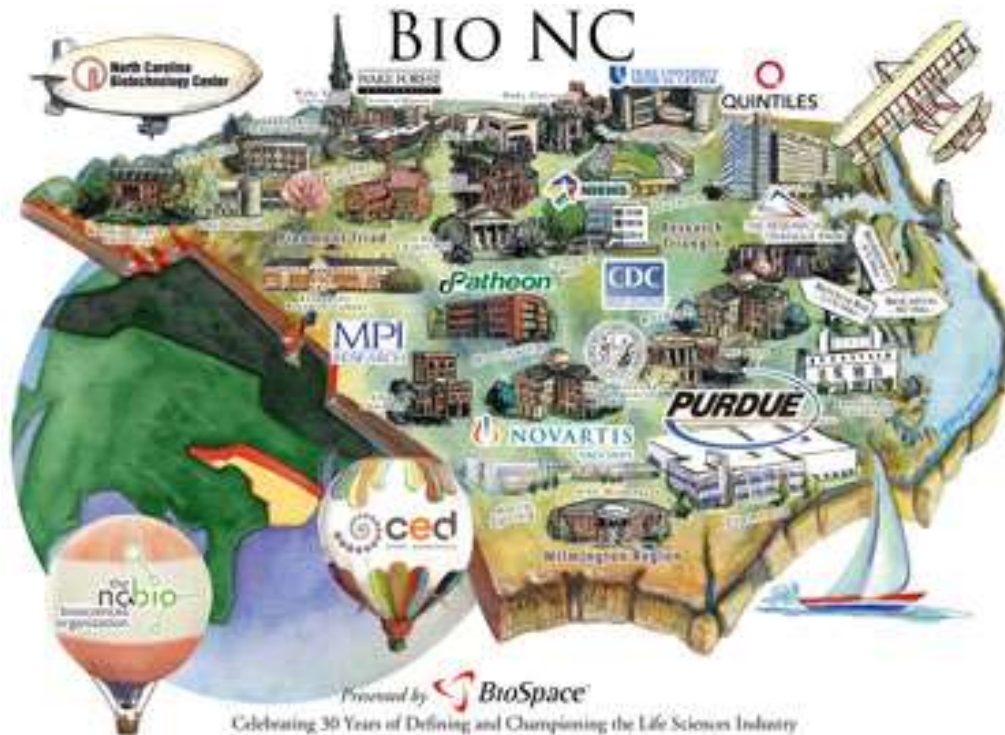


Regulatory changes

Issues with Standard Filling Options



Our view of RTP biotech



Handful of commercialized companies and a lot of clinical/drug development stage companies.

If commercial, complex small-batch manufacturing of high-value drugs.

If clinical, hitting milestones and clinical efficacy.

HOW DOES AUTOMATION OF ASEPTIC FILLING SUPPORT THE SUCCESS OF EACH TYPE OF ORGANIZATION?

The Workcell Concept



The background of the image is a photograph of an industrial aseptic filling workcell. The cell is a large, stainless steel enclosure with its doors open, revealing internal components. Inside, there are several vertical filling nozzles and a central rotating carousel. The interior is illuminated with a red light, which is a common safety feature to indicate that the cell is in a sterile or active state. The overall design is clean and professional, typical of pharmaceutical manufacturing equipment.

vanrx

Pharmasystems Inc.

The Aseptic Filling Workcell

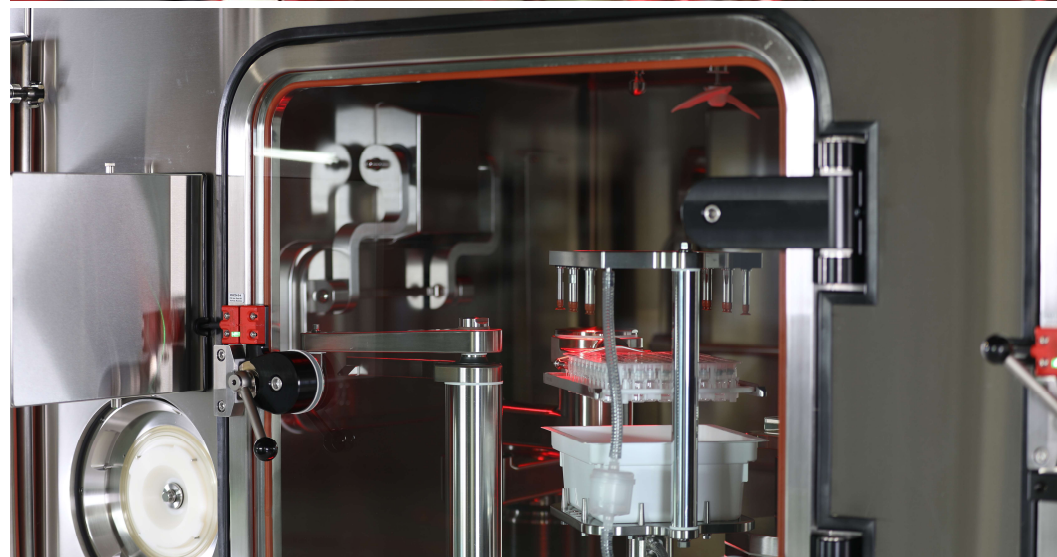
Robotics

Vanrx's unique design specifically for pharmaceutical filling

Designed for cleaning and lowest possible particle generation

All operating mechanisms outside Grade A space

**REPEATABLE
PRECISION
FAST
CHANGEOVER**





Gloveless Isolator

The first completely closed gloveless isolator

Place in Grade C/D cleanroom

Lowest possible risk to drug product

Increases sterility assurance

**REMOVE HUMANS
FROM THE
PROCESS
ALL COMMON
INTERVENTIONS**

DESIGNED OUT

Ready-to-use Containers & Closures

FLEXIBILITY

Filling, lyophilization and closure of containers occurs within the nest.

QUALITY

No glass-to-glass contact and reduced risk of product loss or recall.

STERILITY ASSURANCE

Pre-sterilized and reduced manufacturing complexity.



Vanrx Aseptic Filling Workcells



Microcell Vial Filler

Drug development, clinical trials and personalized medicines.



SA25 Aseptic Filling Workcell

Late clinical trials and commercial manufacturing for vials, syringes and cartridges.



Vanrx Liquid / Lyo Workcell Line

Late clinical trials and commercial manufacturing for vials, syringes and cartridges of both liquid and lyophilized dosages.

Standardization





Pharmasystems Inc.



Focused on Faster

Customer Case Study: Singota Solutions

Background

Business Case

Decision Factors

Equipment Selection

Practical Implications

Current State

