Aseptic Filling Workcells

Gloveless Robotic Isolators for Aseptic Filling

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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

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<tr>
<th>Project</th>
<th>Description</th>
<th>Status</th>
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<tr>
<td>NuThrax™ (AV7909)</td>
<td>Anthrax Vaccine Candidate&lt;br&gt;Adjuvant Vaccine Absorbed with DTP 7909 Adjuvant</td>
<td>Phase 3 Clinical&lt;br&gt;First subject enrollment targeted for 2019</td>
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<tr>
<td>FLU-GIV</td>
<td>Seasonal Influenza Therapeutic Candidate&lt;br&gt;Hyperimmune Platform</td>
<td>Phase 3 Clinical&lt;br&gt;First subject enrollment targeted for 2018</td>
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<td>VLA1601</td>
<td>Zika Virus Candidate&lt;br&gt;Injectable Purified, Inactivated Zika Virus Vaccine</td>
<td>Phase 1 Clinical&lt;br&gt;First subject enrollment targeted for 2018</td>
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<tr>
<td>ZIKV-IG</td>
<td>Zika Therapeutic Candidate&lt;br&gt;Hyperimmune Platform</td>
<td>Phase 1 Clinical&lt;br&gt;First subject enrollment targeted for 2018</td>
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<tr>
<td>UNI-FLU</td>
<td>Universal Influenza Vaccine Candidate&lt;br&gt;Injectable Nanoparticle Universal Influenza Vaccine</td>
<td>Pre-Clinical</td>
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<td>EBX-205</td>
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<td>Pre-Clinical</td>
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### Speed to market and in market

- **NuThrax™ (AV7909)**: Phase 3 Clinical<br>First subject enrollment targeted for 2019
- **FLU-GIV**: Phase 3 Clinical<br>First subject enrollment targeted for 2018
- **VLA1601**: Phase 1 Clinical<br>First subject enrollment targeted for 2018
- **ZIKV-IG**: Phase 1 Clinical<br>First subject enrollment targeted for 2018
- **UNI-FLU**: Pre-Clinical
- **EBX-205**: Pre-Clinical

### Ease of use

### Regulatory changes
Issues with Standard Filling Options
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
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 DESIGNED OUT FROM THE PROCESS ALL COMMON INTERVENTIONS
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

- Build Machine
- FAT
- Install
- SAT
- IQ / OQ
- PQ
- Qualified
- Production

6 Months
6 Months
6 Months
Focused on Faster
Customer Case Study: Singota Solutions

Background

Business Case

Decision Factors

Equipment Selection

Practical Implications

Current State