PARTNERING SOLUTIONS:

Development of the DCVMN Member Database

Peter H. Khoury, Ph.D., MBA
President & CEO
- Objectives of this Partnering Solution
- Ology Bio and our Involvement
- Development of the Database and Status Update
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Objectives of the DCVMN Database

A forum to connect those in need of vaccine fill/finish and/or technical expertise, with those who can provide assistance

- Utilizes excess F/F capacity, lowering overhead costs
- Provides lower cost options than capital investment in F/F for growing companies
- Develops a conduit for future dialog and collaboration
- Valued reference for available manufacturing for drug substance/product, F/F in various containers, analytical testing, and other capabilities (adjuvants, conjugates, spray drying, secondary packaging, etc.)
• Objectives of this Partnering Solution
• **Ology Bio and our Involvement**
• Development of the Database and Status Update
Ology Bioservices at a Glance

  - Berkley, California: Monoclonal antibody development and manufacturing
  - Frederick Maryland: Government Contracting Offices
  - 200+ employees

- Experience
  - Over 20 years of discovery, development and manufacturing

- Best-in-class biopharmaceutical manufacturing facility
  - Multiproduct, multipurpose, single-use capabilities
  - Pilot-scale through Phase-3 manufacturing scale
  - BSL 3-compliant, cGMP capabilities
  - 183,000 Ft² (17,000 M²) highly secured plant with expansion in shell
  - Four ballroom manufacturing suites, accommodating single-use technologies or stainless steel bioreactors up to 2,000 L

- Proprietary technologies for vaccines and monoclonal production
- Over $800 M in Government contracts won to date
BARDA Fill-Finish Manufacturing Network (FFMN)

- HHS/BARDA, 10-year IDIQ structure (indefinite delivery and quantity)
- Therapeutics, vaccines, drug shortage products
- Multiple teaming partners from clinical to commercial
- Liquid, lyophilized
- Multi-purpose, multi-product capabilities
  - Vials
  - Syringes
  - Cartridges
  - Blow fill seal
Benefits of Teaming

- Access Specialized Expertise
  - Adjuvants
  - Preservatives
  - Various container/closure systems
- Fill Excess Capacity
- Emergency Response
On August 8, 2014, WHO declared the deteriorating situation in West Africa a Public Health Emergency of International Concern (PHEIC)

Ology Bio contract awarded Nov 2014

Scope: Formulation and fill of six (6) lots of Mapp Biopharmaceutical’s ZMapp 3-mAb cocktail mix to support clinical study and emergency response

Success
✓ All 6 Lots filled within 2 weeks of DS receipt
✓ Product shipped under quarantine
✓ Product released within 4 weeks
Case Study #2 – Pandemic Influenza Vaccine

- In Support of USG Pandemic Preparation
- Scope: Validate formulation and fill of pandemic influenza vaccine against H7N9
- Ology Bio contract awarded May 2017

**Success**
- Technology transferred and scaled production to 100,000 ten-dose vials
- Process and analytics validated
- Completed Engineering run
- Completed three (3) Process Performance Qualification/Conformation lots
- Product in Strategic National Stockpile
• Objectives of this Partnering Solution
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Establishment of DCVMN Member Service Database

- Initial Survey to Members to gauge interest
- Follow-up questionnaire to collect information
- Verification of data (collated data sent to each company)
- Database interactive interface currently under construction with graphic web design company
- Database to be accessible through DCVMN site
How many vaccine types is your company producing as bulk manufacturer?

1-2 vaccine types: N=15

3-5 vaccine types: N=14

6-10 vaccine types: N=2

Greater than 10 vaccine types: N=0

Percent of Responses
Total Response N=31
DCVMN spare (surplus) capacity annually for filling vaccines?

- None: N=3
- Less than 500,000 doses: N=2
- 500,000 to 1 million doses: N=0
- 1 million to 5 million doses: N=5
- 5 million to 10 million doses: N=1
- 10 million to 20 million doses: N=8
- Greater than 20 million doses: N=11

Percent of Responses
Total Response N=30
What type of filling operations does the facility conduct?

- **Single-dose glass syringe**: N=16
- **Single-dose glass vials**: N=24
- **Single-dose glass ampoules**: N=10
- **Multi-dose glass vials**: N=18
- **Single-dose plastic vials**: N=2
- **Other, please specify**: N=3
- **Plastic dropper, plastic syringes**: N=24
How many types of vaccines is your company filling from bulk received from other manufacturers?

- **1-2 vaccine types**: 16 responses
- **2-5 vaccine types**: 9 responses
- **5-10 vaccine types**: 0 responses
- **Greater than 10 vaccine types**: 0 responses

Percent of Responses
Total Response N=25
If your facility has surplus capacity, are you interested in supporting external projects as fill-finish services for other manufacturers or product Sponsors?

- **Yes**: N=18
- **No**: N=2

Percent of Responses
Total Response N=20
## Using Database to Identify DCVMN Partnership Opportunities

### Developing Countries Vaccine Manufacturing Network

#### Facility Information

<table>
<thead>
<tr>
<th>Company Code, Quality, and Regulatory</th>
<th>Vaccine Products</th>
<th>Facility Information</th>
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<tr>
<td><strong>Filling Facilities</strong></td>
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</tbody>
</table>

**Container Capabilities**

- Single-Dose Glass Syringe
- Single-Dose Glass Vial
- Single-Dose Plastic Vials
- Single-Dose Glass Ampoules
- Multi-Dose Glass Vials
- Multi-Dose Plastic Dropper
- Single-Dose Plastic Syringe

**Special Capabilities**

- Adjuvants?
- Preservatives?
- Lyophilization?
- Spray Dry?
- Conjugation?
- Secondary packaging?

**Interest in Providing Services to External Companies**

- Drug Substance Production?
- Drug Product Production?
- Secondary Packaging?
- Analytical Testing?
Using Database to Identify DCVMN Partnership Opportunities

https://www.dcvmn.org/

**Company Overview**
- **Company name**: Beijing Minshui Biotechnology Co., Ltd.
- **Website**: www.biominshui.com
- **Headquarters Address**: No.35, Shijing Road, Bioengineering & Pharmaceutical Industrial Park, Daxing District, Beijing 102600 P.R.CHINA
- **Manufacturing Address**: No.35, Shijing Road, Bioengineering & Pharmaceutical Industrial Park, Daxing District, Beijing 102600 P.R.CHINA
- **Year founded**: 2004
- **Contact name**: Zhang Qian
- **Contact email**: zhangqian@vip.126.com
- **Contact tel**: +86 10-59613580

**Certifications**
- **ISO 9001 or 14001 Certification**: not confirmed
- **GMP Certificate**: not confirmed

**Product Type Expertise**
- **Number of Live or attenuated viral vaccines**: 1
- **Number of Inactivated viral vaccines**: 3
- **Subunit, recombinant, polysaccharide, and conjugate vaccines**: 7
- **Number of Toxoid (Inactivated toxin) vaccines**: 4
- **Other Product Types**: N/A

**Technical capabilities**

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Searchable fields
Database Easily updated and New Member Information Added
Summary

• DCVMN continues to provide innovative ways to support their members
• This member service database initiative will assist in identifying partners for fill and finish, secondary packaging, analytical testing, and other manufacturing needs
• Once finalized, this service will be offered through the DCVMN.org website

Thank You
Please visit us in person or online at OlogyBio.com