

PARTNERING SOLUTIONS: ***Development of the DCVMN Member Database***

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Capable. Collaborative. Creative.

- 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.)

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Ology Bioservices at a Glance

- **Biologics Contract Development and Manufacturing Organization (CDMO)** headquartered in Alachua, Florida.
 - **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



CLINICAL FILL LINE

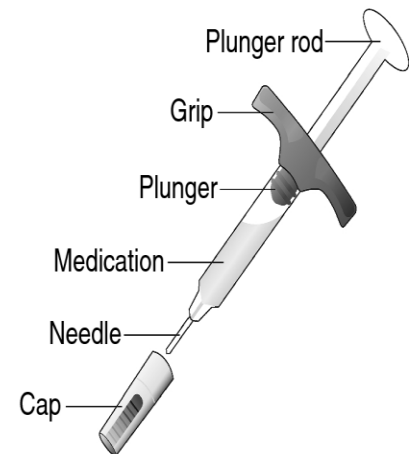
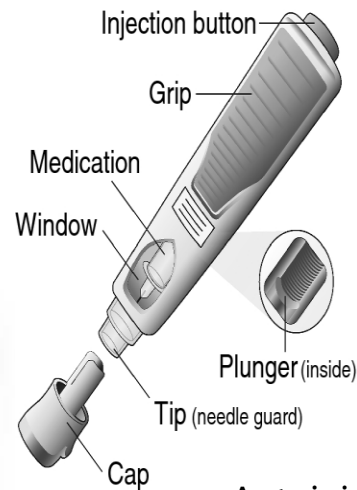


COMMERICAL FILL LINE



Benefits of Teaming

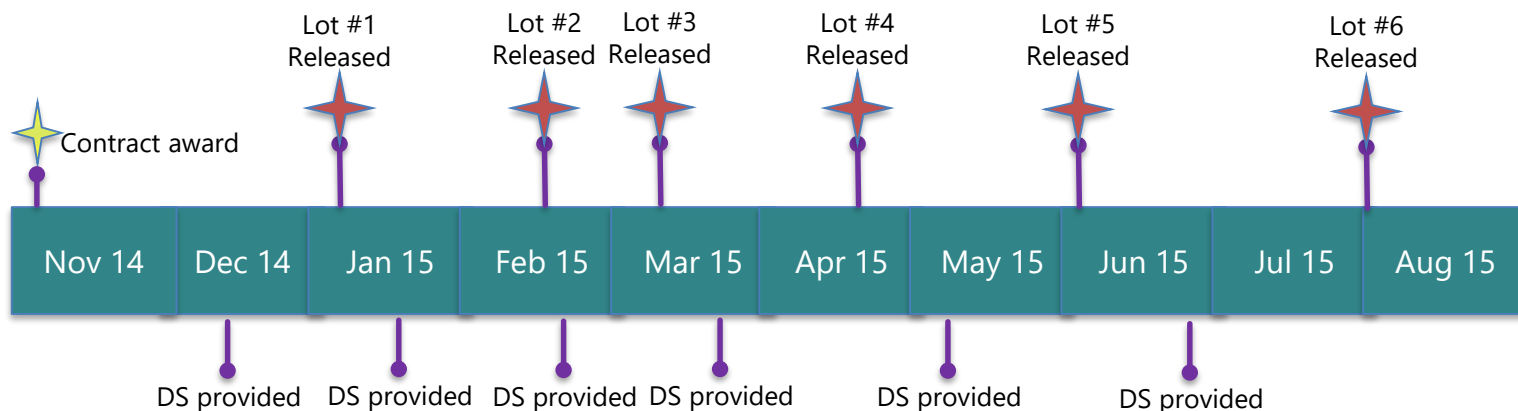
- Access Specialized Expertise
 - Adjuvants
 - Preservatives
 - Various container/closure systems
- Fill Excess Capacity
- Emergency Response



Autoinjector Assembly

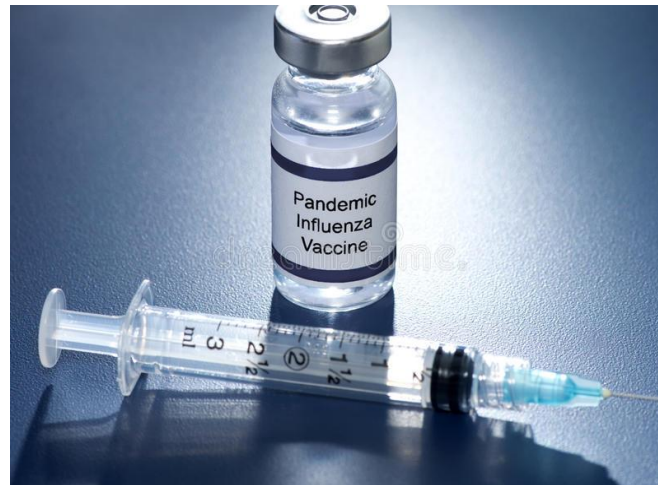
Case Study #1 – Anti-Ebola Monoclonal Antibody

- 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

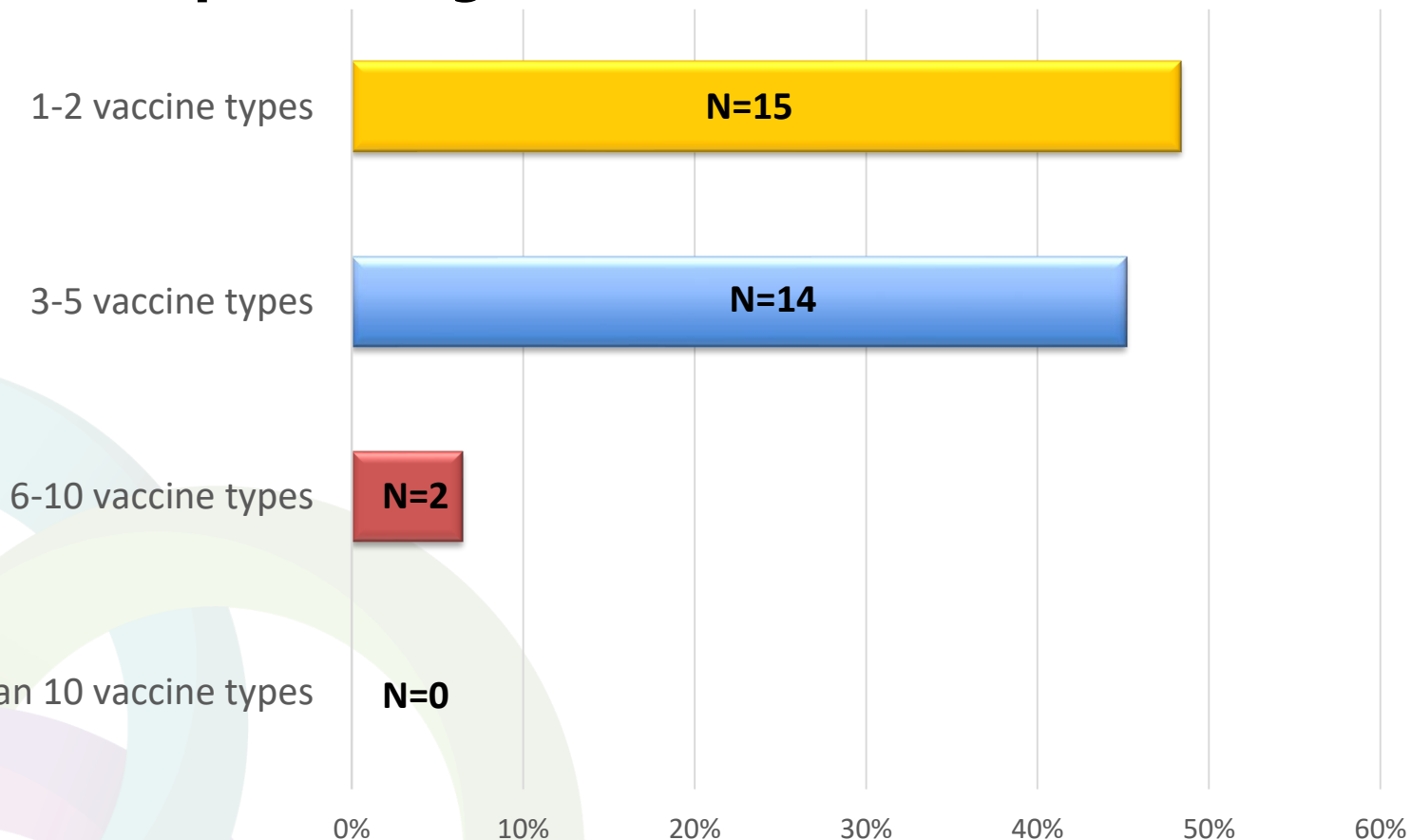


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Establishment of DCVMN Member Service Database

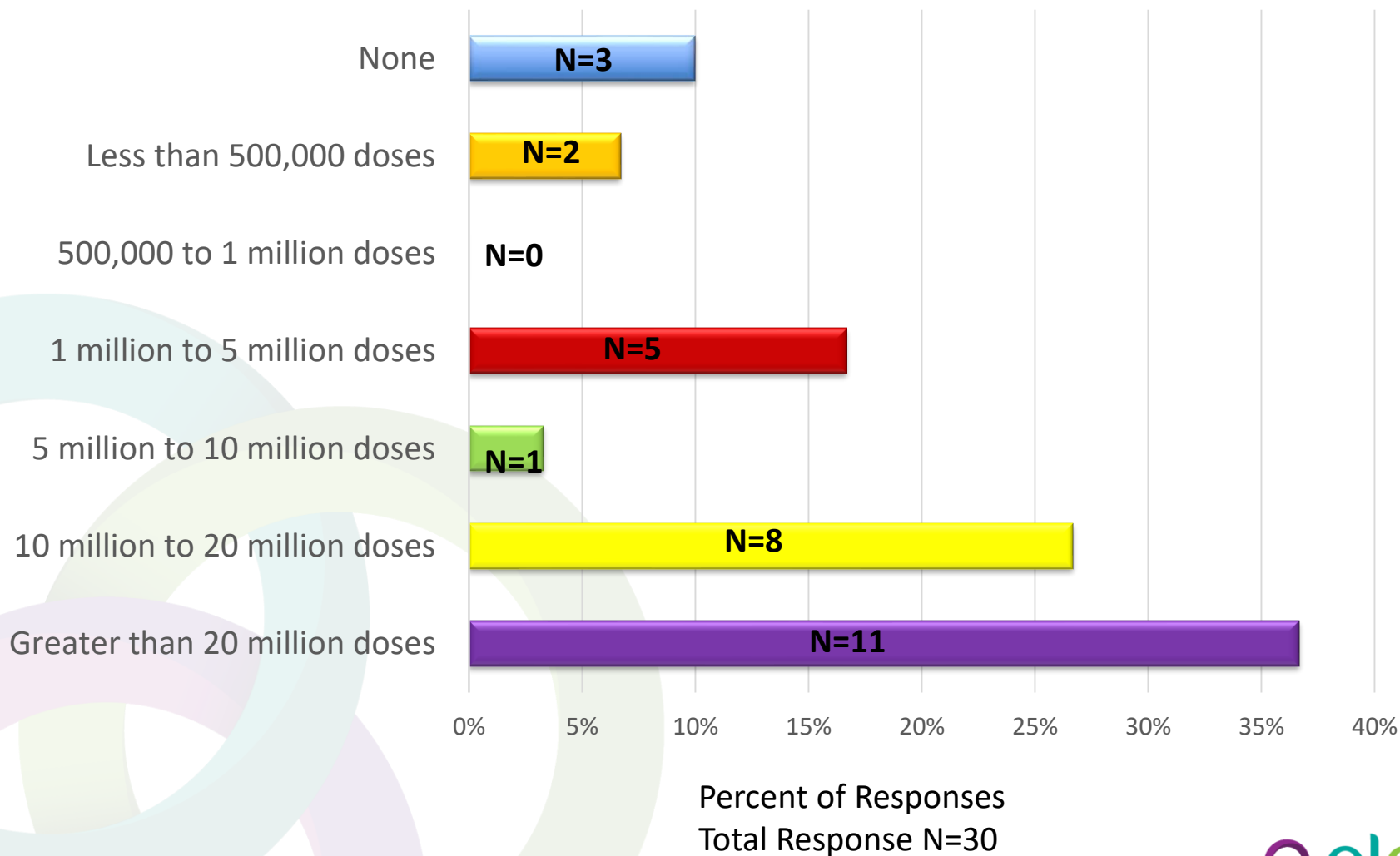
- Initial Survey to Members to gauge interest
- Follow-up questionnaire to collect information
- Verification of data (collated data sent to each company)
- Database interactive interface currently under construction with graphic web design company
- Database to be accessible through DCVMN site

How many vaccine types is your company producing as bulk manufacturer?

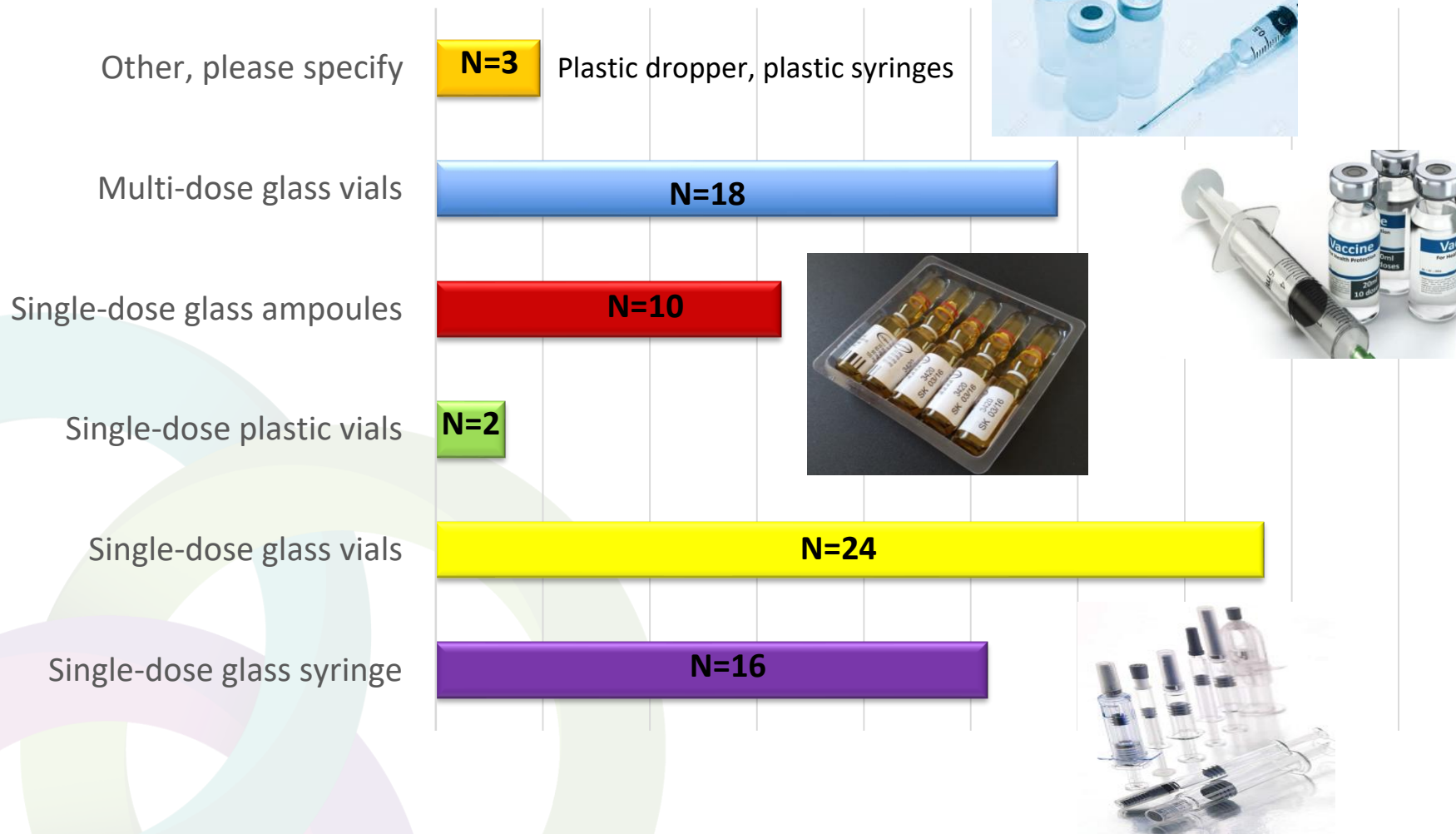


Percent of Responses
Total Response N=31

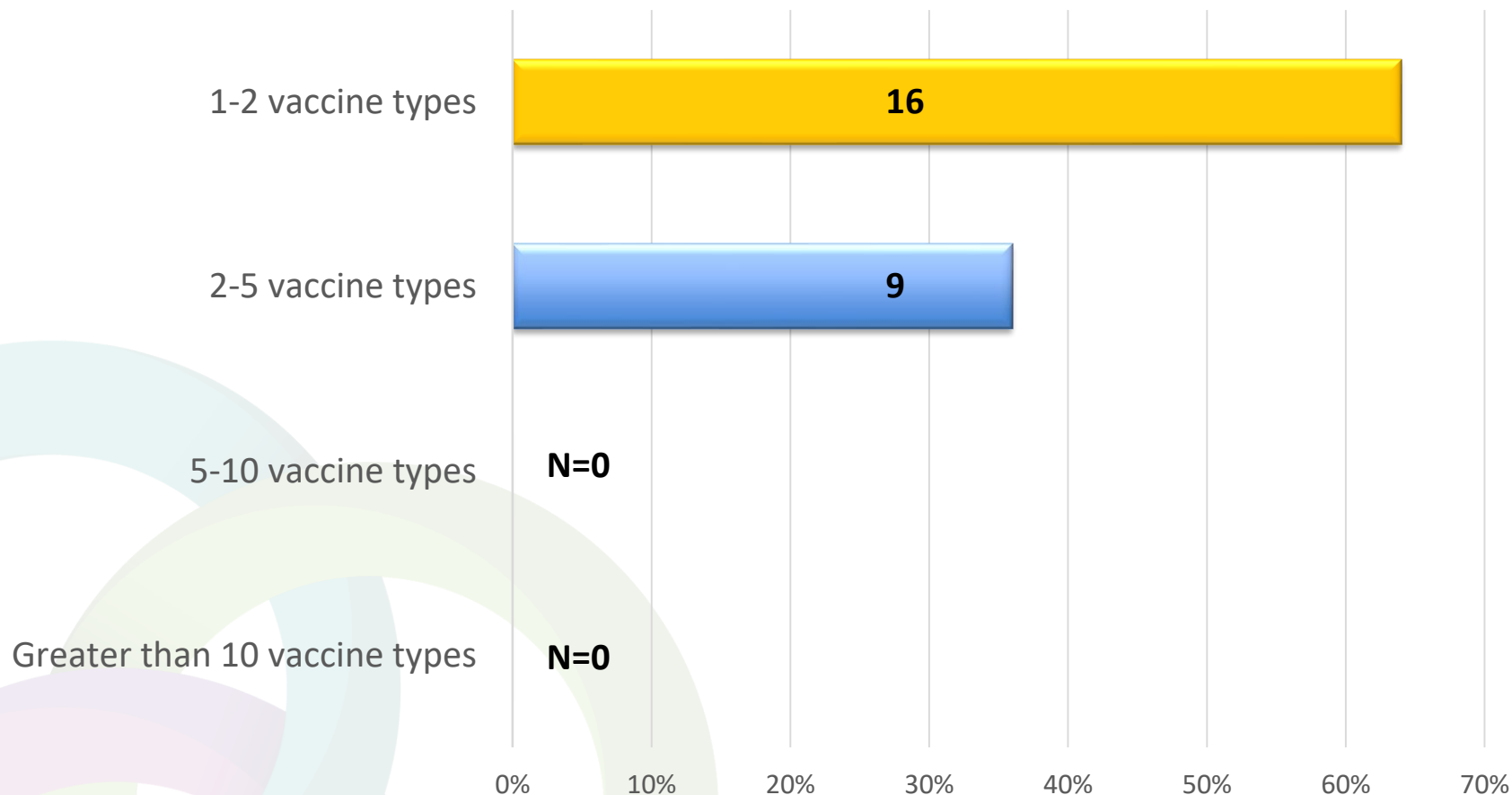
DCVMN spare (surplus) capacity annually for filling vaccines?



What type of filling operations does the facility conduct?

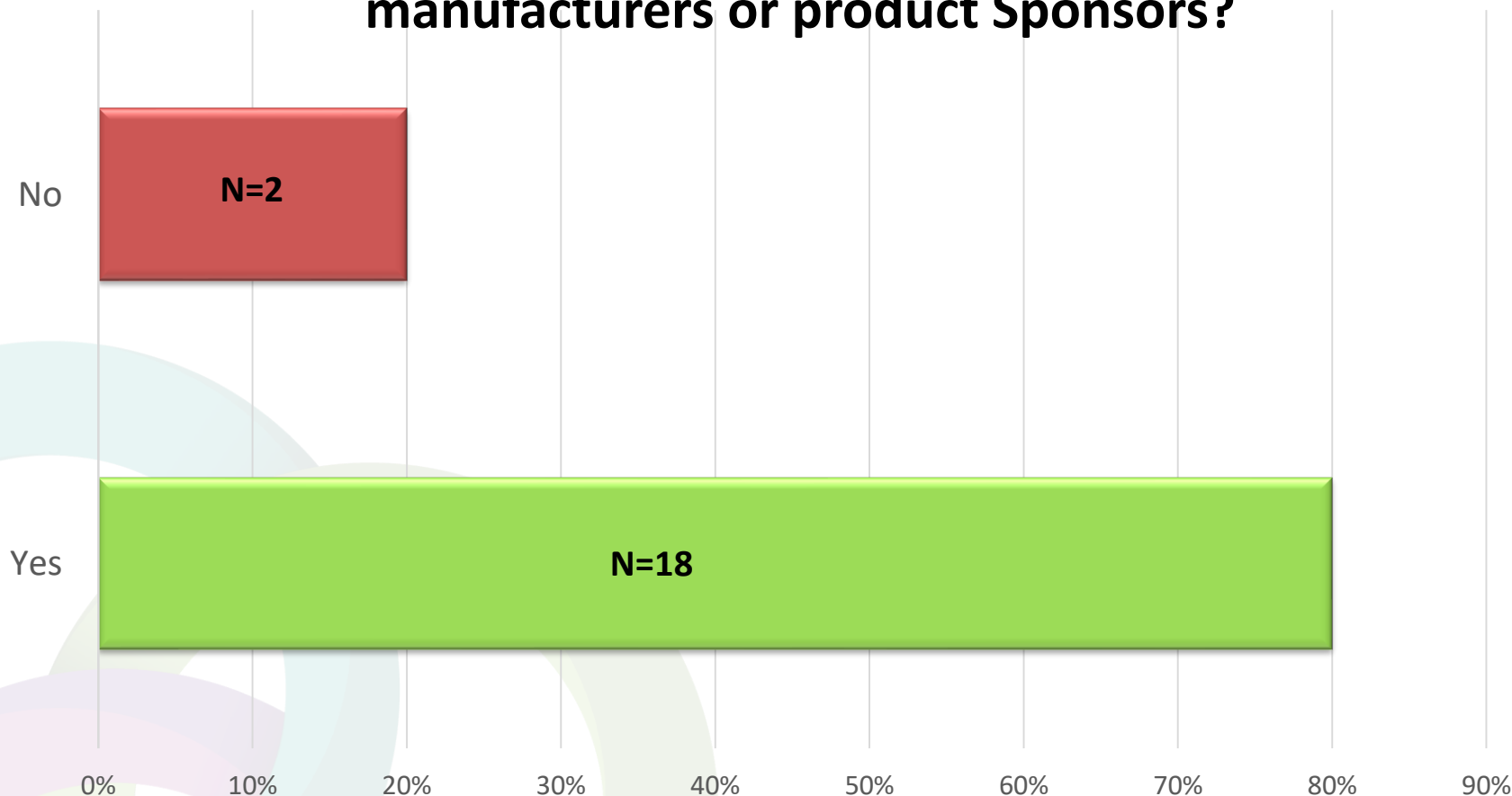


How many types of vaccines is your company filling from bulk received from other manufacturers?



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?



Percent of Responses
Total Response N=20

Using Database to Identify DCVMN Partnership Opportunities

Developing Countries Vaccine Manufacturing Network

Find Company Code 

Company Code, Quality, and Regulatory Vaccine Products Facility Information

Filling Facilities

Number Facility Location 1

Facility Location 2

Single Filling Facility

Multiple Filling Facilities

Filling Lines

Number Location

Single Filling Line No

Multiple Filling Lines

Container Capabilities

Minimum

Maximum

☐ 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

Production Type 1

Production Type 2

☐ Drug Substance Production?

☐ Drug Product Production?

☐ Secondary Packaging?

☐ Analytical Testing?

Using Database to Identify DCVMN Partnership Opportunities

https://www.dcvmn.org/

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Company overview

Company name	Beijing Minhai Biotechnology Co., Ltd.
Website	www.biominhai.com
Headquarters Address	No.35, Simiao Road, Bioengineering & Pharmaceutical Industrial Park, Daxing District, Beijing 102600 P.R.CHINA
Manufacturing Address	No.35, Simiao 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 10-59613590

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

Searchable fields

Database Easily updated and New Member Information Added

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Partnerships portal

Show 10 entries Search:

COMPANY NAME	HEADQUARTERS LOCATION	TYPE OF PRODUCTS	TECHNICAL CAPABILITIES	CERTIFICATION	RESPONSIBLE NRA
Beijing Minhai Biotechnology Co., Ltd.	No.35, Simiao Road, Bioengineering & Pharmaceutical Industrial Park, Daxing District, Beijing 102600 P.R.CHINA	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	CLINICAL DEVELOPMENT CONTAINERS: Glass Syringe , Glass Vials , Ampoule FORMULATION: Adjuvants , Conjugation SERVICES: Analytical Testing , Provide Drug Substance Production Service to External Companies , Provide Drug Product Production Service to External Companies , Service for Live/attenuated , Service for Toxoid	ISO: not confirmed GMP: not confirmed	Certificate of good manufacturing practices for pharmaceutical products for mr, Beijing food and drug administration, 2018
China National Biotech Group Company Limited	16th F/L Fortune Tower, 4 Hui-xin East ST., Chaoyang District, Beijing, China	Number of Live or attenuated viral vaccines: 6 Number of Inactivated viral vaccines: 2 Subunit, recombinant, polysaccharide, and conjugate vaccines: 2 Number of Toxoid (inactivated toxin) vaccines: 0 Other Product Types: N/A	CLINICAL DEVELOPMENT CONTAINERS: Glass Vials FORMULATION: Adjuvants , Conjugation SERVICES: Secondary packaging , Analytical Testing , Provide Drug Substance Production Service to External Companies , Provide Drug Product Production Service to External Companies , Provide Secondary Packaging Service to External Companies , Provide Analytical Testing Service to External Companies , Service for Live/attenuated	ISO: not confirmed GMP: not confirmed	
Company for Vaccine and Biological Production No1 (VABIOTECH)	1 Yersin Street, Hai Ba Trung, Hanoi, Vietnam	Number of Live or attenuated viral vaccines: 0 Number of Inactivated viral vaccines: 3 Subunit, recombinant, polysaccharide, and conjugate vaccines: 1 Number of Toxoid (inactivated toxin) vaccines: 0 Other Product Types: N/A	CLINICAL DEVELOPMENT CONTAINERS: Glass Vials FORMULATION: Adjuvants , Preservatives SERVICES: Secondary packaging , Analytical Testing , Provide Drug Substance Production Service to External Companies , Provide Drug Product Production Service to External Companies , Provide Secondary Packaging Service to External Companies , Provide Analytical Testing Service to External Companies , Service for Inactivated	ISO: Yes GMP: not confirmed	Vietnamese Ministry of Health, 2015
EuBiologics Co., Ltd	6F BomnalAchim BD, Mabangro8, Seochoogu Seoul	Number of Live or attenuated viral vaccines: 0 Number of Inactivated viral vaccines: 1 Subunit, recombinant, polysaccharide, and conjugate vaccines: 0 Number of Toxoid (inactivated toxin) vaccines: 0 Other Product Types: N/A	CLINICAL DEVELOPMENT CONTAINERS: Plastic Vial SERVICES: Analytical Testing , Provide Drug Substance Production Service to External Companies , Service for Inactivated	ISO: Yes GMP: Yes	Inspection by Korean CDC (2011)
GC Pharma	107, lhyeon-ro 30beon-gil, Gijheung-gu, Yongin-si, Gyeonggi-do	Number of Live or attenuated viral vaccines: 1	CLINICAL DEVELOPMENT CONTAINERS: Glass Syringe , Glass Vial	ISO: not confirmed GMP: not confirmed	Every year by multiple regulatory agencies

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

