



NATIONAL MCM RESPONSE INFRASTRUCTURE:

THE FILLING & FINISHING
MANUFACTURING NETWORK
(FFMN) COMPONENT

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October 15, 2015

FFMN Capabilities and Strategies



Well- established CMOs with Fill and Finish expertise in the following:

- Formulation, Fill & Finish Vials and Syringes
- Technology Transfers
- Regulatory Support
- Analytical Development
- Clinical Trial and Commercial Scale lots
- Labeling & Packaging
- Storage and Distribution
- Lyophilization

Support Surge Pandemic Influenza Manufacturing

Support influenza-focused, EID or CBRN contractors who do not have fill finish capabilities already in-house

Additional products being developed through the CIADM.

Support FDA remediation of drug shortage situations

Produce clinical investigational lots, engineering lots, and commercial scale lots



Who is Our Network?



Let's Redefine Possible
a whole new world of possibilities for pharmaceutical companies

Patheon
Performance the World Over®



nanotherapeutics



**BioPharma
Solutions**

The Promise of Science
Realized



COOK
PHARMICA

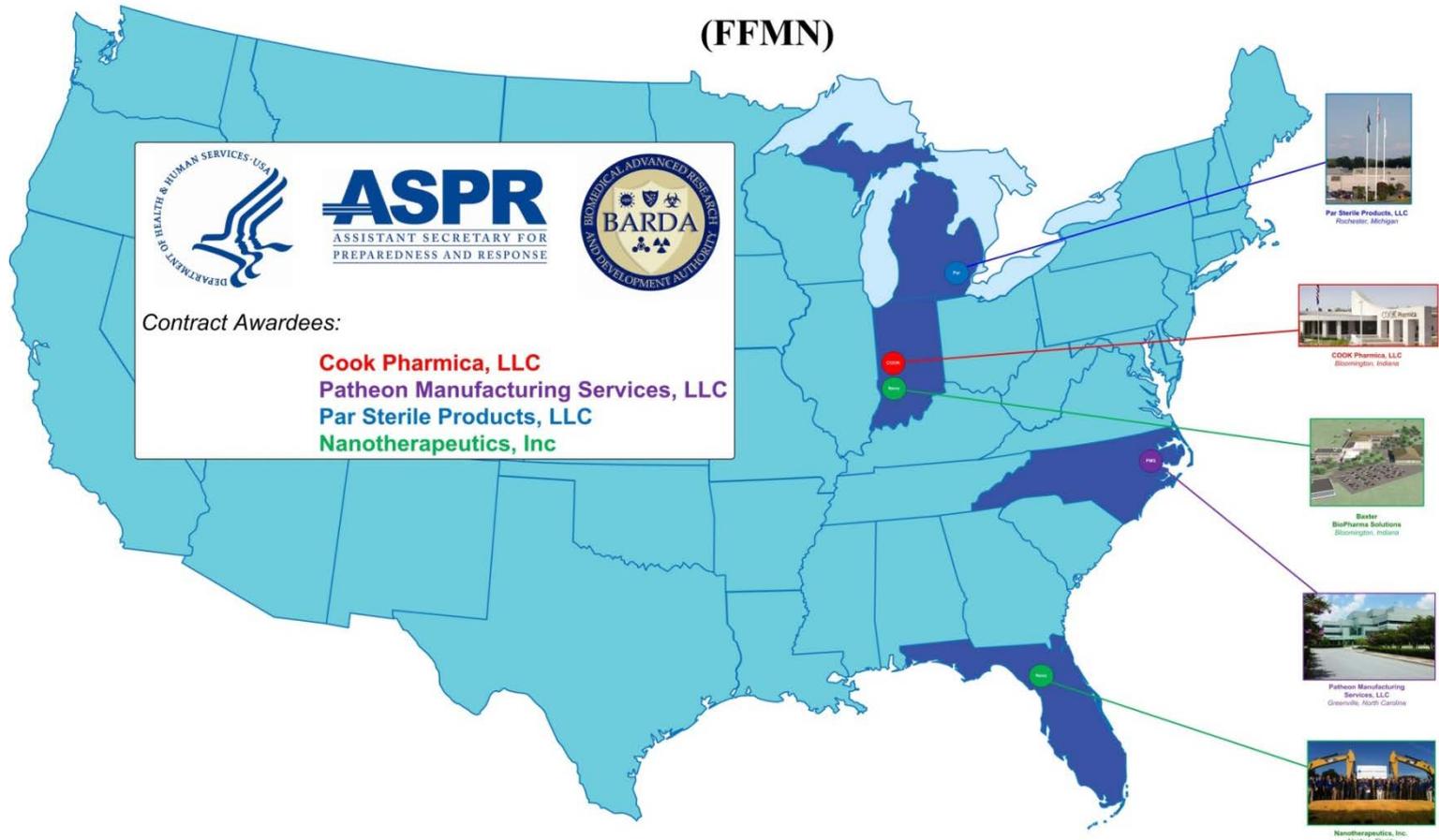


PAR
PHARMACEUTICAL

JHP
PHARMACEUTICALS
Partners For Healthcare Excellence



FFMN Contractors



Objective: Establish a network of existing facilities that are pre-qualified and under contract to fill and finish vaccines/drugs for U.S. Government-contracted manufacturers.



Project Summary

Task Order number	Contractor	Description	Status
1T	All 4 FFMN Members	Tech transfer of Influenza candidate	delays
2T	Nanotherapeutics/ Baxter Biopharma Solutions	Zmapp Filling	Complete- to be extended
3T	Nanotherapeutics/ Baxter Biopharma Solutions	CDER Pathway pilot program for drug shortage product: Magnesium Sulfate Injection Solution Aseptically Filled into 10mL Plastic Syringes	Collaboration with FDA; Task order just started

Four Task Orders Awarded



FFMN TASK ORDER HHSO10033001T

Current Activity

1. CLIN 0001 Establish Agreements with License Holder/Sponsor
2. CLIN 0002A Influenza Technology Transfer

Contractor	Potential Influenza Vaccine Candidate
Cook Pharmica	GSK
Par (formerly JHP)	CSL Biotherapies
Patheon (DSM)	Novartis
Nanotherapeutics partnered with Baxter Pharmaceutical Solutions (BPS)	Nanotherapeutics now owns Baxter's Influenza Technology



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FFMN TASK ORDER HHSO10033002T

Current Activity

1. Task Order 2T Awarded Nov 2014 to Nanotherapeutics- Ebola Response
 - a. Major Subcontractor Baxter Biopharma Solutions
 - b. Supply agreement with Mapp (Product Sponsor) and KBP Bio Processing for BDS manufacturing

2. SOW: Tech transfer, Methods transfer, Filling and Stability studies for 6 x Zmapp monoclonal antibodies (3) cocktail Drug Product lots, shipping and storage.
 - a. All 6 filled lots completed June 2015
 - b. Stability studies in progress
 - c. Multiple shipments to support studies in West Africa (Sierra Leone, Guinea, Liberia)
 - d. Contract modification pending to add 5 more lots to the task order.



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FFMN TASK ORDER HHSO10033003T and 4T

Products
Magnesium Sulfate- Solution based injectable
Succinylcholine Injection- Solution based injectable

1. Pilot Production: Tech transfer of CDER pathway products pilot production program- simple solution Drug Shortage products
 - a. Collaboration with FDA to Identify products to start – used Drug Shortage Index
 - b. Kickoff meeting held 6/30- jointly with FDA
 - c. Scope of work:
 - a. Minor development work at Nanotherapeutics,
 - b. Tech transfer to subcontractor Baxter BioPharma Solutions to include demonstration and process validation lots and stability studies.
 - c. ANDA to be submitted by Nanotherapeutics for both products.
 - d. Period of performance: 18 months



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CDER Pathways

Pilot Production Program

- Collaboration with FDA: Win/Win!
 - FFMN member pilots the regulatory process for CDER regulated products (2)- this serves as a practice test
 - If and when a public health emergency hits, the FFMN is “ready”- its not the first time to follow this pathway
 - Potential remediation of 2 products on the FDA Drug Shortage index
 - New manufacturer and ANDA holder for these products
 - Once successful, other opportunities for assisting drug shortage remediation could be investigated



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FFMN: Anticipated Activities: 1-2 years in the future

- Additional Task Orders for “ZMapp-like” therapeutics (i.e. CHO cell based)- continued Ebola response projects
- Additional RFP for Live Virus Specific Fill capabilities to expand the network- drafted (LVV is a recognized gap)
- Continue to participate as an integral component of the National MCM Response Infrastructure as public health response needs are identified



FFMN Trajectory for the Future

- Confirm Pandemic Influenza Partner
- Tech Transfer Pandemic Candidate
- Establish Pandemic Surge Capacity
- Support CBRN, EID & Influenza Projects

