



**Pharmaceutical Contract Manufacturing & Support Services
with Substantial Project Flexibility**

**** Please contact Luke Plumpton (315-476-7418 EXT 2318; lplumpton@hanford.com)
regarding your contract manufacturing & support services needs.***

Pharmaceutical Contract Manufacturing & Support Services

Outline

- I. Company Overview (P.2)
- II. Manufacturing Capabilities (P.3)
- III. Hanford's Specific Product Type Experience (P.5)
- IV. New Manufacturing Facility – Overview (P.6)
- V. Pharmaceutical Support Services Capabilities (P.7)
- VI. Additional Considerations (P.9)
- VII. Summary and Contact Information (P.11)

Pharmaceutical Contract Manufacturing & Support Services

Company Overview

- Founded by George C. Hanford in 1846, Hanford Pharmaceuticals is the only U.S.-based independent contract antibiotic finisher. Hanford is currently looking to increase business in our core competency of beta-lactam antibiotic manufacturing **but is also diversifying itself outside of our traditional sterile antibiotic capabilities.**
- Hanford is committed to increasing diversification of our product and service offerings and we understand that our 30 years of experience in aseptic processing can be more broadly utilized. In order to capitalize on our experience, we have acquired an 84,000 square-foot facility and are currently developing the space for manufacturing, warehousing and laboratory support services of non beta-lactam products.
 - This facility will include both aseptic processing capability as well as space that can be used for non-sterile product manufacturing.
 - The facility will also provide the space necessary to increase Hanford’s ability to offer our broad range of contract pharmaceutical support services, including Validation Services, Analytical Methods Development, Regulatory and Document Support, Quality Control Testing and OSHA/FDA Required Safety and GMP Training, to name just a few.
 - The facility has sufficient space to accommodate multiple production installations with both clinical and commercial-scale output capabilities.
 - Hanford expects the facility to be ready for contract manufacturing & support services projects by Q4 2010.

Pharmaceutical Contract Manufacturing & Support Services

Manufacturing Capabilities

- Hanford manufactures both sterile and non-sterile pharmaceutical and animal healthcare products for the North American market.
- Hanford has focused on aseptic manufacturing and there is general agreement in the industry that aseptic processing of sterile products is the single most difficult type of product to manufacture.
- Hanford has four-decades of experience as a company in aseptic processing and the cumulative experience of our personnel measures in the 100's of years.
- Our senior level scientists and technologists have worked in the strict regulatory environment that is aseptic processing for 20 or more years.
- Key members of our management team have decades of experience in product manufacturing, client care, and support activities.
- Hanford manufactures product both to be sold under our own labels and contract manufacturers for a number of multi-national pharmaceutical and animal health care corporations and undergoes frequent audits and inspections from both our client base and regulatory agencies such as the FDA.

Pharmaceutical Contract Manufacturing & Support Services

Manufacturing Capabilities (Cont'd)

- Success in manufacturing in such a highly regulated industry requires a breadth of capability in a wide range of disciplines. Hanford has the following organizational disciplines to support our sterile and non-sterile manufacturing operations:
 1. **Quality Control:** Hanford maintains well-equipped and expertly staffed laboratories to conduct both chemical and microbiological analysis required by current global regulations. These scientists also conduct environmental monitoring and in-process testing activities, both of which have great regulatory significance.
 2. **Quality Assurance:** Hanford has a cadre of experienced technical managers who ensure that our quality systems meet global requirements. Their efforts involve not only the assurance of our own manufacturing and release of production lots, but also ongoing self-assessment and continuing process and quality improvement.
 3. **Regulatory affairs:** Our regulatory affairs professionals handle all communications with regulatory agencies and our customers regulatory professionals.
 4. **Product Development:** Hanford has the expertise to assist customers in the development and regulatory approval of their pharmaceutical products, we are fully equipped to handle pilot production, product analytical development, stability programs, and to assist in the preparation of regulatory submissions of all types.
 5. **Validation and Process Control:** Hanford handles all of our validation both prospective and ongoing in-house. Our process control professionals are able to handle any validation challenge including the preparation of protocols, validation master planning, execution of qualification studies and final report writing.
 6. **Manufacturing:** Hanford has manufactured liquid, liquid suspension, and powder aseptic products in a wide range of container closure systems. Product types we have manufactured include sterile vials and syringes as well as a wide variety of non-sterile products in various formats.

Pharmaceutical Contract Manufacturing & Support Services

Hanford's Specific Product Type Experience

Current Projects:

- Powder Filling
 - Sterile vials
 - Non-sterile pouches
- Powder Formulation (sterile)
- Liquid Filling
 - Non-sterile syringes
- Liquid Formulation
 - Non-sterile syringes
 - Plastic containers

Active Development:

- Tablets
 - Blending
 - Drying
 - Filling
 - Packaging

Previous Processes:

- Liquid formulation and filling
 - Sterile vials
- Various non-sterile ointments and creams
 - Formulation
 - Filling
 - Packaging

Pharmaceutical Contract Manufacturing & Support Services

New Manufacturing Facility - Overview

- Hanford recently acquired approximately 84,000 square feet of undeveloped space that we are currently developing into a non-beta lactam manufacturing facility.
- This facility will enable Hanford to apply all of our manufacturing and pharmaceutical support experience to the manufacture of a broader range of products.
- Our new facility is being designed as a general pharmaceutical manufacturing facility so as to give our clients ample opportunity to customize their space and equipment to exact specifications.
- Clients can partner with Hanford so that they can leverage our production management, support, quality and regulatory experience in a setting developed to meet their specific needs.
- Manufacturing space for both sterile and non-sterile products will be developed and a modular approach will be used to ensure maximum flexibility and ease of conversion.
- The facility will be spacious enough to accommodate pilot and clinical scale manufacturing as well as full-scale commercial production.
- Hanford can apply our knowledge and experience to meet specific customer needs and we can tailor our level of support to meet customer requirements. We can also make room available to customers who need space in which their own product development and manufacturing specialists can work.
- Hanford can supply as much or as little support as each client requires and we can do so within a full GMP setting.

Pharmaceutical Contract Manufacturing & Support Services

Pharmaceutical Support Services Capabilities

- **Process and Equipment Validation:**
Installation Qualification, Operation Qualification, Performance Qualification, Cleaning Validation, Instrument Calibration Program, Protocol Writing, Execution of Validation and Final Report Writing services are available.
- **Analytical Methods Development and Validation (Chemical and Microbiological):**
Provides method development to current USP guidelines.
- **Quality Control Routine Testing:**
cGMP compliant testing utilizing USP/NF compendial methods for Raw Material and Finished Product Testing. HPLC (isocratic and gradient) Gas Chromatography, Wet Chemistry and Physical Chemistry testing, Sterility Testing utilizing Isolator Technology, Kinetic and Gel Clot LAL testing capabilities.
- **Regulatory Support:**
Assistance with ANDA and/or ANADA submissions as well as assistance with electronic submissions to OGD or CVM.
- **Product Stability Testing:**
Stability testing throughout product shelf life including assay testing, physical and wet chemistry testing, impurity, LAL, and sterility testing.
- **Supplier Sourcing:**
Provides expertise in sourcing Active Pharmaceutical Ingredients (API) and excipients.
- **Quality Assurance Services:**
Provides Batch Record Review, Document Approval and Quality Oversight of all Pharmaceutical operations.

Pharmaceutical Contract Manufacturing & Support Services

Pharmaceutical Support Services Capabilities (Cont'd)

- **Labeling Services:**

Label development process (from design through printed material approval) of labels, inserts/outserts and cartons, expertise in FDA regulations, barcodes and RSS codes, review and proofreading skills, computer skills, current GMP procedures for label control, established relationships with printed material vendors.

- **GMP Compliance/Audit Support:**

Provides on site or paper audits of manufacturing facilities to help ensure GMP compliance. Offers technical assistance in regards to GMP compliance as outlined in the CFR.

- **GMP Training:**

GMP training is required at the time of hire and is completed as part of a two-day orientation. Continuing education in good manufacturing practices occurs throughout the year. Hanford can provide the same training to your staff that our employees receive. GMP courses provide instruction in job specific topics such as environmental monitoring and restroom sanitation as well as broader, theoretical subject areas including participation in external audits and inspections.

- **OSHA Safety Training:**

Includes job specific information (i.e., forklift operation, respiratory protection) and general safety training (i.e., proper lifting techniques, chemical handling).

- **Non-Sterile Penicillin Clinical Support:**

Approximately 400 square feet of floor space with 10 foot ceiling height. Climate controlled - 65F @ 45% RH. Electrical utilities of various voltage levels (480V, 240V, 208V, 3 phase, 60Hz and 120V, 1phase, 60Hz). Compressed air – 80 psi. House steam – 50 psi. Water for injection and pure steam available.

Pharmaceutical Contract Manufacturing & Support Services

Additional Considerations

- **FDA Relationship**

- Hanford has established an excellent reputation with the FDA, consistently outperforming other pharmaceutical finishers in annual audits. Following our most recent FDA audit, Hanford received no 483s, which are a list of items an FDA investigator believes demonstrates deviation from current Good manufacturing Practices (“cGMPs”). Management believes the number of 483s issued to the Company is consistently much lower than most of our competitors and attributes this success to Hanford’s modern, well equipped facilities and highly-trained employees.

- **Laboratories for Product Development and Quality Control Testing:**

- Hanford maintains fully equipped and staffed analytical testing laboratories capable of evaluating all APIs, excipients, components (vials, syringes, stoppers, packaging materials, etc.) and final products to ensure they meet all established quality specifications. The company is fully capable of conducting any quality control analysis and like all Hanford operational departments, the laboratories have undergone frequent FDA inspections and customer audits to ensure their compliance with regulatory and industry requirements.
- The Company’s chemistry laboratories are fully-equipped with gas and high performance liquid chromatography systems, as well as particle size determination systems. Hanford is also equipped with full product stability testing capabilities, including temperature and humidity controlled chamber that can be used for the support of both marketed product and products under development.
- The Company also maintains a microbiology laboratory to conduct testing on excipients and APIs. In addition to this analytical testing role, the microbiology laboratory also conducts the microbiological environmental monitoring required to support Hanford’s aseptic processing lines. The Company was among the first to implement Isolator Technology for critical sterility testing, which is performed on both incoming sterile APIs and finished product. To ensure maximum reliability in sterility testing, Hanford installed its first isolators in 1993. In 2006, the Company updated to a newer generation of Isolator equipment. Hanford has two Steris VHP-1000 vapor phase hydrogen peroxide decontamination systems to ensure that the isolators are decontaminated to current FDA and USP requirements.

Pharmaceutical Contract Manufacturing & Support Services

Additional Considerations (Cont'd)

- **Process Control and Validation Department:**

- The Company maintains a comprehensive process control department that reports to quality assurance. Process control undertakes the activities most often termed “process validation” in the pharmaceutical industry, but at Hanford, they play a role that is far broader than validation alone. Process Control manages all of the Company’s validation activities, including installation, operational and process qualification of all equipment. Process Control also undertakes all protocol writing, the execution of validation studies and final report writing. Many of these reports are used in Hanford’s submissions for regulatory approval of new products or improved processes.
- Validation at Hanford is a multi-disciplinary activity, particularly in areas such as process simulation testing of aseptically-filled products and packaging, where employees performance is a critical component in process control and therefore product quality. It is generally recognized that the aseptic production of sterile products is the single most difficult production undertaking in the pharmaceutical industry. The regulatory requirements for demonstrating that an aseptic process is in a validated state-of-control are both rigorous and specific. The Company is required to comply with the same regulatory guidelines and to achieve the same demonstrated levels of performance as Fortune 100 multi-national pharmaceutical companies. For a relatively small company such as Hanford to fully comply with current industry best practices requires a process control discipline capable of operating at a very high level of efficiency.
- In addition to validation, Process Control undertakes process improvement initiatives and engages in support of all new product development or line expansion. The scientists in Process Control are also proficient in risk analysis techniques that are so vital to both validation planning and problem resolution with the modern pharmaceutical quality system. Regulations require that each process undergo a periodic, usually annual, reassessment and retesting of process control status. This activity, often known as revalidation, is also the responsibility of Process Control, which maintains the specific written procedures that define the scope of this work.

Pharmaceutical Contract Manufacturing & Support Services

Summary and Contact Information

- Hanford Pharmaceuticals, founded in 1846 in Upstate New York and still privately held, is among the most respected of contract manufacturers in the United States.
- Our company's dedication to quality and ability to efficiently deliver superior products and services has been proven since our inception.
- Hanford's experience includes liquid and powder filling as well as tableting. The Company is also experienced in handling suspensions and other complex formulations.
- Feel free to contact the company to discuss your needs as we aggressively increase our capacity for new projects. Hanford will be pleased to consider your specific requirements for both manufacturing and pharmaceutical support services.

***Please contact Luke Plumpton (315-476-7418 EXT 2318; lplumpton@hanford.com)
regarding your contract manufacturing & support services needs.***