



OUR PHILOSOPHY

At **CUSTO**pharm, we realize our success depends on the success of our clients. Therefore, our purpose is to serve our clients not have our

clients serve us. We will provide guidance based on our expertise, but the final decision is always that of our clients. We tailor each of our services based on our clients' needs providing a seamless integration with our clients' current processes. This adaptability assures the most efficient, effective and economical approach for each client project—the cornerstone of our philosophy.

PROJECT MANAGEMENT

CUSTOpharm has extensive experience in project management. This service is included with all of our development services. Our clients receive status updates of their projects via reports and Gantt charts. Our clients are updated on the status of their project(s) and aware of any project delays, if applicable, as they occur.

SOURCING OF PRODUCT MANUFACTURING

CUSTOpharm has established strong relationships with many contract manufacturing organizations (CMOs) both in the US and abroad to enable our clients to effectively manufacture a variety of dosage forms whether for use in clinical trials or commercial production. We specialize in



injectable dosage forms, including lyophilized and cytotoxic compounds. However, we also have relationships with oral, ophthalmic, otic and nasal CMOs. These relationships enable our clients to meet aggressive timelines.



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OUR FOCUS

CUSTOpharm is a customer-focused service company that provides personalized cost-effective chemistry and manufacturing controls (CMC) and regulatory support to companies with limited resources and those seeking to expand into new areas.

CUSTOpharm has a strong background in product development, manufacturing and



regulatory affairs (specifically as it relates to electronic submissions). This background allows us to visualize the "big picture" of our clients' projects with a marketable finished product as the ultimate goal. This "big picture" approach places

CUSTOpharm ahead of other competitors, which focus on specific tasks, not the finished product.

OUR SERVICES

- ◆ PROJECT MANAGEMENT
- ◆ SOURCING OF PRODUCT MANUFACTURING
- ◆ REGULATORY SUPPORT
- ◆ US AGENT SERVICE
- ◆ TECHNOLOGY TRANSFER
- ◆ PRODUCT DEVELOPMENT
- ◆ CONTRACT MANUFACTURING
- ◆ PUB-ASSIST
- ◆ THE **CUSTO**pharm PROGRAM

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REGULATORY SUPPORT



CUSTO^{pharm} continues to be a pioneer with eCTD submissions. To date, **CUSTO^{pharm}** has submitted more than 50 submissions in the eCTD format. We were

the first to submit an ANDA completely in the eCTD format and have been preparing submissions in the eCTD format for more than four years.

CUSTO^{pharm} has developed an eCTD submission process that is both cost effective and does not utilize costly and complicated software. This approach to submissions does not utilize a "black box" approach but rather customizes each file written for our clients' products. This ensures our ability to quickly troubleshoot problems if they arise. The end product is a FDA compliant validated submission in the eCTD format. Our "big picture" approach is most applicable for our regulatory solutions because we always keep a marketable product as our ultimate goal.

CUSTO^{pharm} rapidly integrates the dynamic FDA and ICH trends as they pertain to the eCTD submission and requirements thereof. In addition to submission preparation and assistance, our services include SPL label preparation and we anticipate utilizing the electronic gateway by mid 2008. We understand that some organizations have difficulty utilizing electronic submissions and/or the CTD format. We work with our clients to explain procedures and develop a solution to meet the clients' needs and the FDA requirements.

US AGENT SERVICE

Our US Agent service provides a pathway for foreign pharmaceutical companies interested in expanding beyond local markets and desiring to enter the US market. **CUSTO^{pharm}** works with our clients to ensure compliance with US cGMPs and oversees the regulatory process.

For foreign generic companies, the main advantage obtained is that a commercial marketing partner does not need to be selected prior to the submission process. As approval nears, a marketing partner can be selected. This additional time benefits our clients ensuring they receive the best marketing partner and ultimately the best possible price for their product.

TECHNOLOGY TRANSFER

During the progression of clinical trials, a drug product will need to be transferred from the clinical supply site to a commercial manufacturing site. Additionally, financial or other factors may require that a product be transferred between manufacturing facilities. **CUSTO^{pharm}** has established a systematic approach to ensure an effective technology transfer between two manufacturing facilities while avoiding disruptions in clinical or commercial product supplies.

PRODUCT DEVELOPMENT

CUSTO^{pharm}'s development expertise allows our clients to focus on non-clinical, clinical, marketing and other aspects of drug development and distribution. Employing our services decreases our clients need to utilize valuable resources on product development activities such as analytical validation and formulation development.



At **CUSTO^{pharm}**, we can facilitate development with our clients' current laboratories or we can assist our clients in identifying appropriate laboratories to ensure that project timelines are not delayed, and that our clients' needs are met.

CONTRACT MANUFACTURING

Being a customer focused company **CUSTO^{pharm}** has evaluated the various options available for the manufacture of the sterile liquids. Based on this evaluation, **CUSTO^{pharm}** has developed a cost effective strategy whereby smaller and virtual pharmaceutical companies have access to contract manufacturing at prices similar to companies that possess their own manufacturing facilities without the need to cover the large overhead associated with maintaining a facility. Please contact us for additional information regarding this new service.

PUB-ASSIST

In light of **CUSTO^{pharm}**'s regulatory endeavors, a need developed for publishing software to perform a final 'submission functionality' check prior to validation and subsequent submission to the regulatory agency. Pub-Assist is the publishing tool that works as an Adobe Acrobat® plug-in developed by **CUSTO^{pharm}** Regulatory Professionals for Regulatory Professionals, which allows our clients and customers to perform four common batch processing tasks required for all PDF documents. Pub-Assist can perform the following operations:

- ◆ Checking Hyperlinks and Bookmarks
- ◆ Setting Zoom Level to Inherit Zoom
- ◆ Setting Initial View of Documents
- ◆ Setting the PDF Version

Using Pub-Assist can decrease the time associate with the Quality Control (QC) review for submissions and eliminate errors experienced by those viewing the submissions. Pub-Assist can be used regardless of how the submission is prepared or created. Pub-Assist is used in submissions prepared by **CUSTO^{pharm}** and is available as purchasable software for customers. Technical support and validation assistance is also available.

THE CUSTO^{pharm} PROGRAM

The **CUSTO^{pharm}** Program is our turnkey program combining all of our services described herein. Our clients select a generic product that they would like to sell commercially in the US and/or abroad. **CUSTO^{pharm}** works with drug substance suppliers and CMOs to determine the best pricing for development and costs for commercial production. This allows our clients to determine if the product is commercially feasible before spending significant funds.

CUSTO^{pharm} oversees the analytical and formulation development, manufacture of the stability batch(es) and stability testing. **CUSTO^{pharm}** then prepares and files an ANDA submission in the eCTD format with the FDA. The final product of this service is an approved ANDA. If desired, this service can be extended to oversee the process validation of the drug product. The degree of client involvement in the product development and regulatory process can be modified to suit our clients' needs.