

Contract Services

QUALITY COATING MANUFACTURING

The Steps to Contract Coating

IDENTIFY NEEDS:

Working closely with an AST technical representative, our customers define the properties needed in a coating or surface treatment.

FEASIBILITY STUDY:

AST will treat a small lot to demonstrate the applicability of the coating.

DEVELOPMENT WORK:

Generally, some fine tuning of the coating or process is needed in order to optimize results. Our staff works with the customers in this stage to ensure the changes are cost effective and practical for future production. ISO 9001:2008 and ISO 13485 guidelines are followed.

VALIDATION:

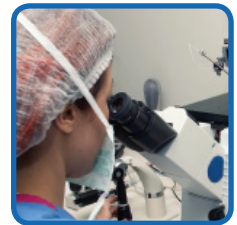
A validation protocol will be developed and the study run. A formal report will be prepared and customer specific SOP's will be written.

APPROVAL:

Upon customer approval, the process is formally transferred to the manufacturing for routine contract services.

Facilities

AST Products maintains three class 100,000 cleanrooms and one class 10,000 cleanroom. General laboratory and office space is at AST's disposal as well. Housed in a 22,000sf building, AST's contract coating services can not only coat your medical devices but also handle procurement and storage requirements.



Commitment to Quality

In 2009, AST upgraded its quality system to meet the requirements of the ~~ISO 9001:2008~~ and ISO 13485 standard. Not only does AST carefully control its processes and documentation, it also commits significant resources to continuous improvement and customer satisfaction.



Availability

AST is committed to fast turn-around of quality coated parts. Its technical staff is available to answer any questions and to provide continual support to all customers.



PARTNERSHIP APPROACH

AST partners with its customers from beginning to end. Our customers have complete access to AST's considerable technical expertise throughout the device design and development process. By working with customers every step of the way, small design changes can be made early in the process that prevent huge delays and overruns late in the game. Along with the coating chemistries, a customized, easy-to-use process is developed under strict ~~ISO 9001:2008~~ and ISO 13485 design control. Our partnership support does not end with the finalization of coating formulation or product design. We work with the customers to ensure smooth and trouble-free implementation at their or at AST's facilities. To accelerate the approval of new devices, AST's experienced staff continues to provide assistance throughout the regulatory approval process and product introduction.



9 Linnell Circle, Billerica, MA 01821
T: 978.667.4500 | F: 978.667.9778
www.astp.com