



METHOD DEVELOPMENT SERVICES

Rapid coating method development and validation services for medical device coatings

ON THE SURFACE
We touch life first

METHODS

*Be a winner in the race
to market with our proven
START NOW™
Stage-gated process*



In the race to market, any delay can mean millions of dollars of lost revenue.

METHOD DEVELOPMENT SERVICES

Rapid Coating Method Development

Validated processes and protocols are utilized to optimize Harland coating technology to deliver a reliable coating method for your device and coating performance needs.

World class medical device companies are leveraging their resources by collaborating with surface enhancement experts.

We are set to handle the small lot sizes and fast turnaround needs of development and market launches.

Each lot of products we coat is backed up with rigorous inspection and testing and is shipped with complete documentation to support both prelaunch and launch requirements.



METHODS

World class coating performance

- Robust process ready for production
- FDA/CE regulatory support
- SO 13485 quality system
- Dedicated methods laboratory

Speed to market matters.

With today's state-of-the-art medical device coatings, the coating performance is dependent on the Method of application as much as the coating chemistry.

Harland's START NOW program brings your coating process quickly through development and validation, ready for production either in Harland's Manufacturing Services or in your own facility with one of Harland's automated coaters.

Throughout the program, speed to market is foremost in our mind.



Initialization

At the onset of each program we quickly work to understand your performance requirements, economic targets and production volume goals. With this understanding we are able to share best practices and clearly explain options and benefits of different approaches, and discuss the chemistry products available to fulfill your specific needs.



Feasibility

With your requirements in mind, we perform rapid proof of concept coating services on your samples, inspect and test them and return them with a comprehensive technical report.

Prototype Development

Using the experience gained from the outcome of the feasibility phase, we optimize the surface enhancement chemistries and manufacturing process used to produce your parts. We also provide coating services for any quantity of prototype parts required for your development needs.

Validation (DOE/OQ / PQ)

Using statistical methods and design of experiments, we find the process limits for coating your device, identifying the high and low limits of the variables that influence the production of a good part.

With the confidence obtained with a successful Operational Qualification (OQ) we will design and perform a statistically driven Process Qualification study to ensure the target process produces coated parts that meet the specification.

Small Runs

As your product advances through the development process, Harland's Method Development is there to deliver fast turnaround coating services to support pre-clinical studies, clinical trials and market launch quantities of coated devices.

Launch Your Device!

We provide complete training and implementation support if you choose to transfer the process to your facility. In addition to the initial start-up support we are available to provide ongoing refresher training and validation support.

Harland's Method Development Services save you time and resources, freeing you to focus on other critical device development issues.

START NOW



Be confident that production of your device is under control.

THE 4M FRAMEWORK™

Harland manages all of these elements as an integrated program to provide you with a complete surface enhancement solution tailored to precisely meet your particular technical, functional and economic requirements.



MATERIALS — proprietary chemistries that enable advanced surface enhancement on your medical devices, healthcare disposables or life science products. Harland provides unique, world class chemistry platforms for solving customer surface enhancement challenges.

METHODS — processes and protocols to effectively and efficiently apply and cure surface enhancing materials. Harland creates and validates robust methods that optimize the integration of Materials and Machines to meet your product's requirements.

MACHINES — automated systems designed specifically to apply and test advanced Materials on your device. Engineered to meet your technical, commercial and operating requirements including throughput and total cost of ownership.

MANUFACTURING — with either Harland Contract Coating Services or customer- owned coating operations. Harland is uniquely positioned to offer a full spectrum of surface enhancement manufacturing options based on your manufacturing strategy and volume requirements.

Total Solution

As a total solution provider, Harland Medical Systems will work with your team through the entire project, providing feasibility and prototype coated devices, process development (OQ and PQ), regulatory and automation support.

Whether you ultimately choose to take advantage of Harland Medical Systems' ISO13485 certified contract coating capabilities or coat your devices in house, you can be assured of total support through the entire process.

Radically reduce and control the surface friction of your medical device.

Lubricent® UV

Lubricent UV coatings reduce friction forces as much as 98%. This performance enhances the device's ability to navigate through tortuous anatomical pathways while reducing tissue damage and adding to patient comfort.

The photochemical covalent bond to the substrate produces superior adhesion and wear-resistance while minimizing particulate formation.

Lubricent UV is compatible with the substrate materials typically used in the construction of medical devices.

Transform your medical device into a powerful weapon in the fight against healthcare associated infections.

Bactigent® CHX

Broad-spectrum antimicrobial coatings are a powerful weapon in the fight against health care associated infections.

Bactigent CHX features the highly effective chlorhexidine precisely dosed and delivered right from the surface of your medical device.

Engineered to provide the elution profile required by the clinical needs of your device and applications.

Bactigent CHX is effective against the most common gram negative and gram positive bacteria associated with health care associated infections.



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