Infosys®
Navigate your next

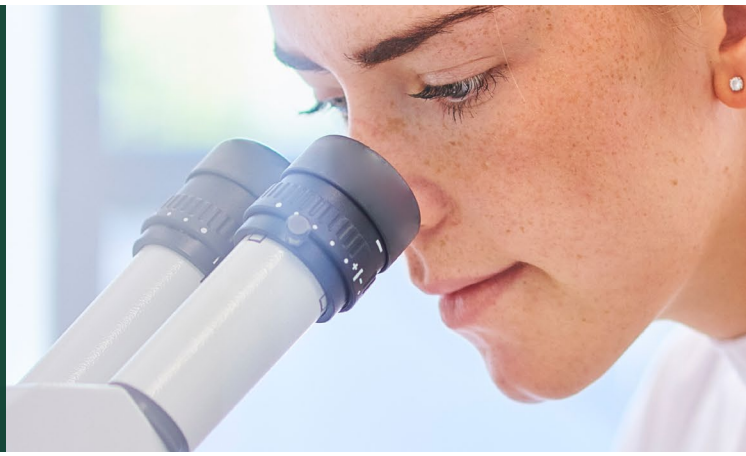
MECHANICAL DESIGN SERVICES AND EMERGING MARKETS COE

Overview

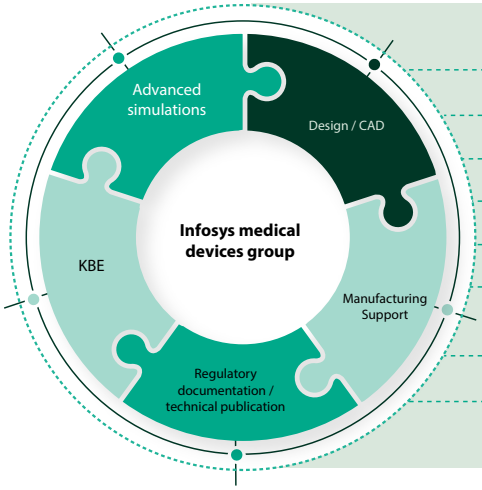
Medical devices companies across the globe are pressed hard to innovate more with less. They are driven by the following industry happenings:

- US healthcare reform placing emphasis on showing value to end customer
- Tighter metrics and GPO (Group Purchasing Organizations) evaluating and awarding contracts for medical device purchases
- Slow growth in developed markets and growing emerging markets; needing either a complete revamp or redesign of products
- Contrasting scenarios of tightening regulations in developed markets and a lack of regulatory frameworks in growth markets

Infosys medical devices practice offers complementing services that could help a global medical device company address many of these challenges efficiently.



Infosys mechanical services overview



- Sustenance engineering – manage fielded products from launch to obsolescence
- Manage CAPA - root cause analysis, impact analysis & implement changes
- Quality, yield improvement initiatives – receiving, supplier & OEM processes
- RoHS compliance – identify gaps, source and verify compliant parts
- Regulatory documentation support – prepare and maintain DHF / risk file
- Packaging and labeling design – create drawings & artwork, qualify supplier and component, verify and launch
- Manufacturing process validation support – perform IQ/OQ/PQ documentation

1. Design / CAD services

- Build parametric 3D models of parts and assemblies from design tables with built-in formulas and validation features
- DFX: Design for manufacturability, design for assembly and design for biocompatibility
- CAD / PDM platform migration, integrate CAD tool with PDM / PLM
- Reverse engineering, 2D to parametric 3D model

2. Manufacturing support services

- Process validation support including performing DOE (design of experiment) studies, IQ, PQ, and OQ studies
- Review / audit existing manufacturing processes to improve yield and quality

3. Regulatory documentation / technical publication services

- Create and maintain documentation for compliance with regulatory requirements
- Perform DHF (Design History File) review to analyze gaps, and remediate to ensure regulatory compliance
- Ready-to-use Infosys DHF remediation framework accelerates DHF review and remediation process

- Design and publish technical publication such as product user manual, service manual, and IFU (Instructions For Use)

4. Knowledge Based Engineering services

- Automate repetitive design tasks using KBE (Knowledge Based Engineering) methodology for product design to ensure first-time-right design and reduce rework
- Create easy-to-use web based KBE tools integrated into CAD systems

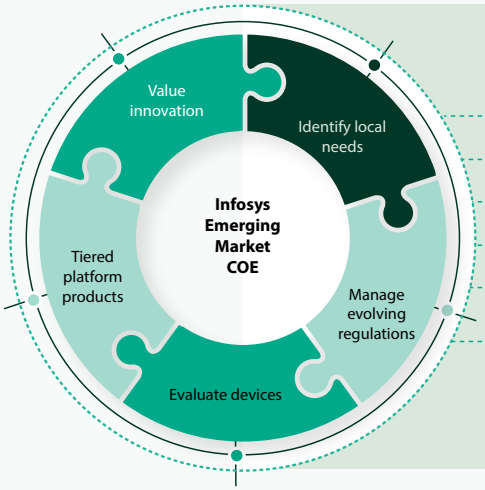
5. Advanced simulations using numerical models of devices and organs / tissue

- Perform engineering simulations to analyze and validate medical device systems and components
- Focus areas include multi-physics simulations and probabilistic parameter sweep studies

Emerging markets CoE (Center of Excellence)

Infosys medical devices practice is equipped to offer end-to-end capabilities – from the scratch development or device re-design for emerging markets.

Emerging markets CoE offers services such as market studies, benchmarking analysis, Voice of Customer (VoC), market vs. feature vs cost analysis and support services along with traditional R&D services in hardware (mechanical and electronics) and software areas.



- Device re-purposing analysis: Evaluate suitability for emerging markets
- Elicit requirements: Leverage Infosys relationships with hospitals
- Value innovation: Localize R&D, sourcing to deliver value
- Perform animal and human clinical trials for new therapies
- Life extension: Re-processing medical devices

Infosys value proposition

- ISO 13485 certified mature engineering services group with 400+ medical device engineers
- Experience in Class III and Class II full life cycle device design and regulatory support
- Engineers with an average experience of 10+ years on mechanical design of Class III and Class II devices
- Dedicated medical devices training academy and proven knowledge management framework
- 1500+ strong mechanical services group – design, CAD, advanced engineering simulations, knowledge based engineering (KBE), technical publications, manufacturing engineering
- Alliances with premier R&D labs, large research hospitals for medical devices development

For more information, contact askus@infosys.com

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