

THE DESIGN PROCESS FOR MANUFACTURING:

COMPLEXITIES IN MEDICAL ENGINEERING



The design process for manufacturing medical devices is multifaceted and challenging, requiring careful attention to detail and a deep understanding of engineering, biology, and regulatory standards. The journey from initial design to a market-ready medical device involves many complexities that significantly impact both engineering and manufacturing aspects.

Biocompatibility Considerations

One of the primary complexities in medical engineering is ensuring biocompatibility. Biocompatibility goes beyond selecting appropriate materials such as titanium, stainless steel, or PEEK. It is the end result of a complex cascade of local and systemic responses of the human body to contact with a medical device, responses that are generally not even fully understood by experts in the field.

This interaction is influenced by numerous factors, including the raw material composition, manufacturing residues, surface finish, cleaning processes, packaging, sterilisation, and the intended use of the device. Therefore, a thorough biocompatibility evaluation is critical.

To navigate this complexity, the ISO 10993 standards provide a comprehensive framework for biological evaluation. This evaluation process involves a risk assessment that addresses numerous questions about material composition, potential contaminants, surface characteristics, and manufacturing residues. For instance, it chemical composition affected by the manufacturing process and its potential degradation within the human body. This risk-based approach ensures that the device meets the stringent requirements for safe human interaction.



10993

Manufacturing Process and Residuals

The manufacturing process itself introduces complexities that affect the final product's biocompatibility and performance. During manufacturing, various substances such as oils, greases, polishing pastes, coolants, and detergents are used, which may leave residues on the device. These residues can adversely affect the device's safety and performance. Thus, effective cleaning and passivation processes are essential to remove these contaminants. Additionally, the packaging and sterilisation processes must be scrutinised to ensure they do not introduce new contaminants or alter the device's chemical composition. For instance, certain sterilisation methods might induce chemical changes that could affect the device's performance or biocompatibility.

Clinical Investigation and Regulatory Compliance

Another layer of complexity in the design and manufacturing of medical devices is the need for rigorous clinical investigations and regulatory compliance. In the European Union, medical devices must undergo conformity assessment by a notified body to ensure they are safe and perform as intended. For implants and higher risk (Class III) devices, an important part of the conformity assessment is the evaluation of the results of a pre-market clinical investigation performed with the device.

Clinical investigations require coordination among various stakeholders, including governmental authorities, ethics committees, principal investigators, sponsors, manufacturers, hospitals, contract research organisations, and patients. Each stakeholder plays a critical role in ensuring the investigation is ethically conducted, scientifically valid, and compliant with regulatory standards. The principal investigator, for example, is responsible for the clinical conduct of the investigation, while the sponsor (individual, company, institution or organisation) oversees the overall management and financial setup.

Documentation and approval processes are extensive, with each regulatory body and ethics committee requiring specific information. This ensures that the device's safety and efficacy are thoroughly evaluated in the clinical setting before it reaches the market.

▼ 3D printed implant, BAAT Medical



3D printed cervical cage, BAAT Medical ▶

How BAAT Medical Can Help

BAAT Medical is well-equipped to handle all these complexities with our design, engineering, manufacturing and regulatory expertise. Our close collaboration with suppliers and deep knowledge of regulatory requirements for both EU and US markets allow us to create efficient testing plans,

reducing both costs and time to market. Partnering with BAAT Medical helps you to understand and align the various roles and stakeholders and their needs, and we can generate the complete required documentation for you. BAAT can even act as Legal Manufacturer for your device and that is what makes us stand out. ■

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