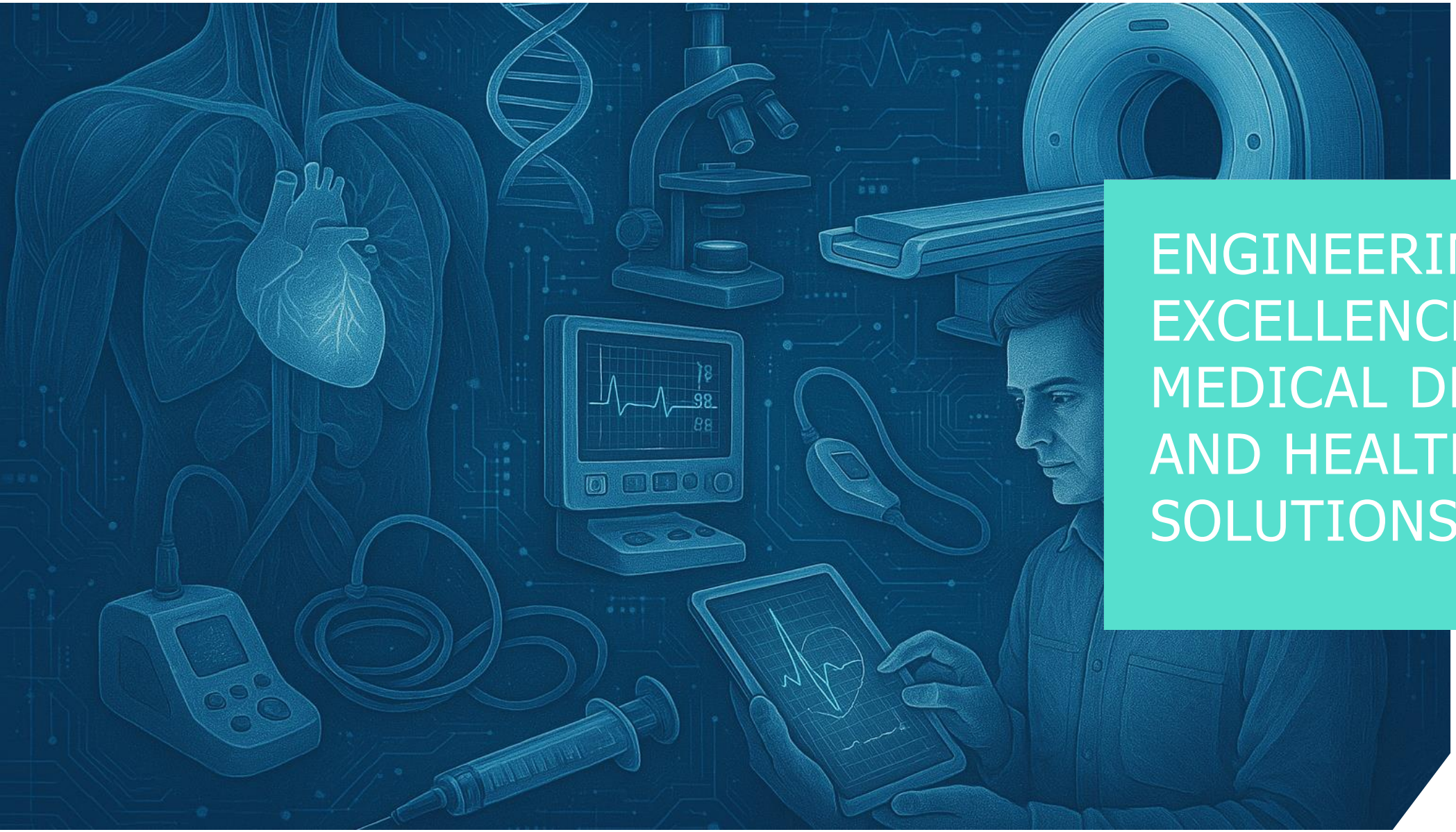
DECOS
HEALTHTECH



ENGINEERING EXCELLENCE FOR MEDICAL DEVICES AND HEALTHCARE SOLUTIONS

INTRODUCTION

Innovating Medical Device with Advanced Product and Systems Engineering Services

At Decos, we empower medical device manufacturers and healthcare innovators with cutting-edge Product Engineering and Systems Engineering services. From concept to compliance, we ensure your solutions are compliant, regulatory-ready, and future-proof—helping you bring safe, efficient, and high-performing medical technologies to market.

Industries we serve

Medical device manufacturers | Healthcare technology companies | Medical device OEMs.

PRODUCT ENGINEERING SERVICES

Decos delivers end-to-end Product Engineering Services for medical devices, ensuring seamless integration of design, development, compliance, and testing. From concept to commercialization, we help you build market-ready, regulatory-compliant, and high-performance healthcare solutions.

PRODUCT ENGINEERING SERVICES

- End to End Product Development
- Hardware Design
- Mechanical Design
- Compliance to Standards
- Product Lifecycle Management
- Remediation
- Engineering Change Request (ECRs)
- Product Security Gap Assessment
- CAPA & RCA Activities
- REACH & RoHS Management
- Reliability & Environmental Testing
- Firmware Development
- Software Development
- Audiologist (SME)Support

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END TO END PRODUCT DEVELOPMENT

New Product Development (NPD) & New Product Introduction (NPI)

From ideation to full-scale production, we help you navigate the complexities of product development, ensuring a smooth transition from prototype to market-ready device.

Feasibility Studies

Before investing in full-scale development, we evaluate the technical, regulatory, and economic feasibility of your product concept. Our feasibility assessments help de-risk your project.

Usability Studies

A well-designed medical device must be intuitive, safe, and effective. We apply human factors engineering (HFE) principles to optimize usability and meet regulatory expectations.

User Research & Task Analysis

Understanding clinician and patient workflows.

Human Factors Validation

Conducting usability studies for FDA and EU MDR compliance.

Design Iteration & Risk Mitigation

Enhancing safety through iterative testing.

Risk & Reliability Engineering

Mitigate risks and enhance device reliability with robust failure mode analysis, risk mitigation strategies, and environmental stress testing.

Quality & Regulatory Compliance

Ensure seamless adherence to FDA, EU MDR, and global regulatory requirements, accelerating certification and approvals.

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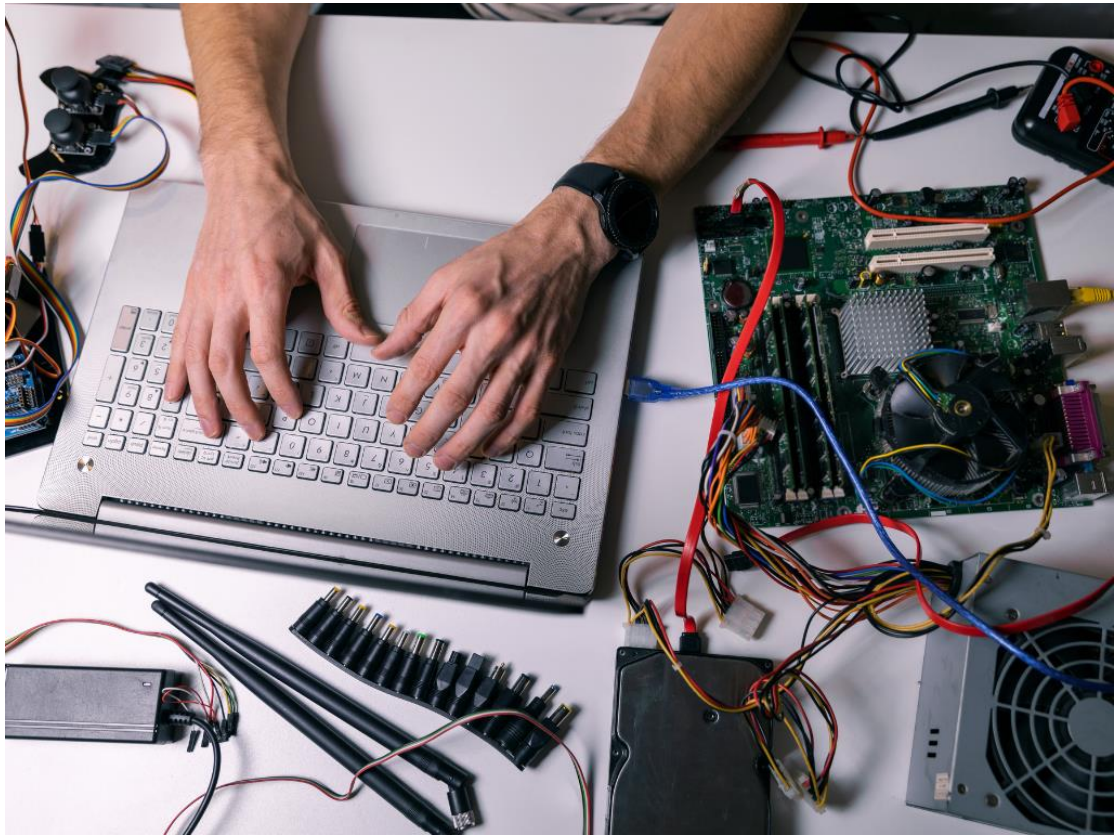
HARDWARE DESIGN



Analog Frontend & Digital Design

We design high-performance analog and digital circuits tailored for medical applications, ensuring precision and signal integrity.

Component Selection & Schematics

We help you select components that meet medical-grade standards, optimizing for longevity, performance, and cost.

Multi Layered PCB Design

We develop compact, high-density PCB layouts, optimizing for EMI/EMC compliance (IEC 60601) and ensuring signal integrity in complex medical devices, thermal management, and efficient routing for high-performance electronics.

Prototyping

From 3D modeling to rapid prototyping, we bring designs to life with advanced simulation, material selection, and mechanical analysis to ensure durability and efficiency, enabling you to quickly test and iterate on your product design.

MECHANICAL DESIGN

- **Material Design and Analysis:** Creating detailed designs and performing simulations to predict product performance. This includes stress analysis, thermal analysis, and fluid dynamics, ensuring that the product meets all functional and safety requirements.
- **Selection and Qualification:** We guide you through choosing the right materials for device safety, biocompatibility, and regulatory approval.
- **Product Database Management:** We offer services to facilitate real-time collaboration among design, engineering, manufacturing, and supply chain teams by moderating and managing data in Engineering Data Management, Product Data Management, and Enterprise Resource Planning tools.
- **Simulation and 3D Modelling:** Before moving into production, we simulate real-world conditions to optimize device design and performance:
    - Finite Element Analysis (FEA) for stress and fatigue testing
    - Thermal and fluid dynamics simulations for cooling and airflow optimization
    - Vibration and shock analysis to ensure device durability

COMPLIANCE TO STANDARDS

- **EMI / EMC (IEC 60601):** Medical electronic devices operate in critical environments, where electromagnetic interference (EMI) and electromagnetic compatibility (EMC) are key concerns. At Decos, we help ensure your device meets IEC 60601 standards, to ensure that electronic products do not interfere with other devices and can operate reliably in their intended environment.
- **ISO 13485** specifies requirements for a quality management system for medical devices. Compliance with ISO 13485 ensures your medical device meets global quality standards for design, development, and manufacturing.
- **ISO 14971:** Proactive risk management is critical in medical device development. We help implement ISO 14971-compliant risk management strategies.
- **IEC 62304** provides guidelines for the lifecycle processes of medical device software. We ensure Software development in accordance with IEC 62304 lifecycle processes.

ISO 13485:2016 CERTIFIED FOR EXCELLENCE IN QUALITY AND COMPLIANCE

Delivering trusted, regulatory-compliant solutions for healthcare and medical device innovation.

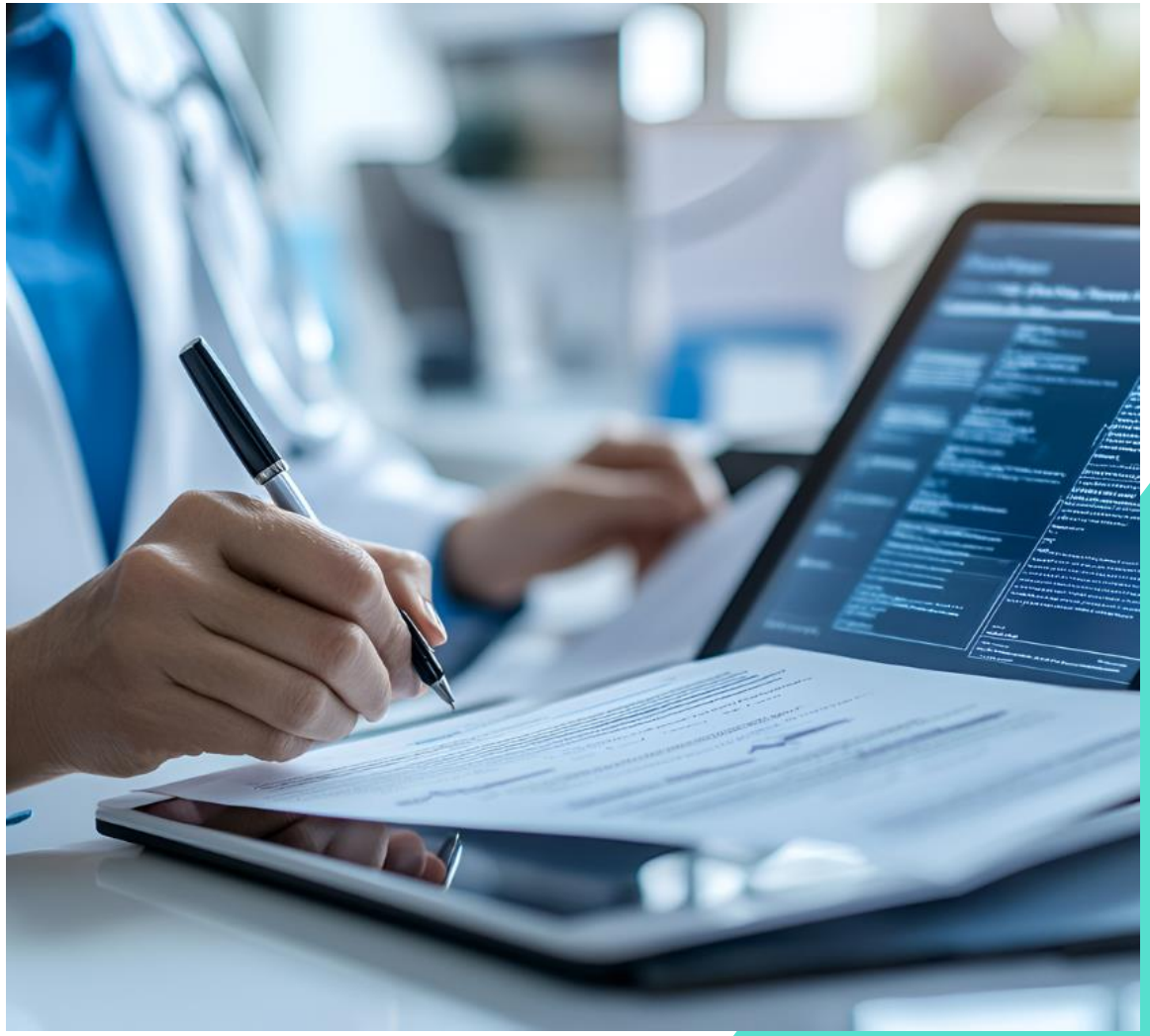
PRODUCT LIFECYCLE MANAGEMENT

DHF & DMR Creation / Maintenance:

Regulatory authorities require a well-maintained Design History File (DHF) and Device Master Record (DMR) for medical devices.

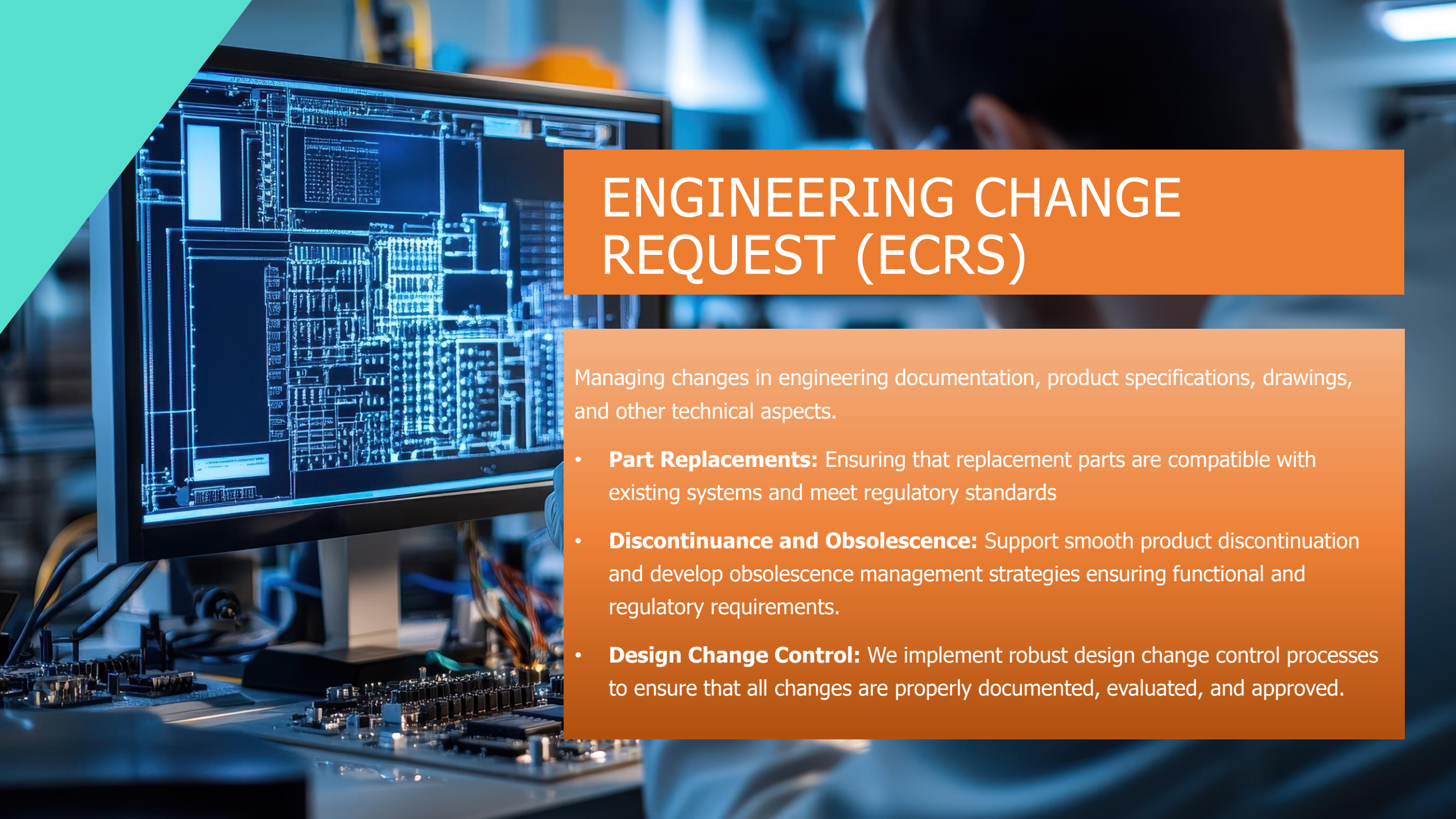
We ensure:

- DHF creation & maintenance in line with FDA 21 CFR Part 820 and EU-MDR
- DMR development & updates, ensuring all manufacturing details are properly documented
- Gap analysis & remediation to bring existing documentation up to regulatory standards



REMEDIATION

- **DHF & DMR:** We create, maintain, and remediate Design History Files (DHF) and Device Master Records (DMR), ensuring compliance with regulatory requirements.
- **FDA, MDD & EU-MDR Requirements:** We provide expert guidance on FDA, MDD, and EU-MDR requirements, ensuring your product meets all regulatory standards.
- **Audit Support:** We assist with audit preparation, response, and representation, ensuring a smooth and successful audit process.



ENGINEERING CHANGE REQUEST (ECRS)

Managing changes in engineering documentation, product specifications, drawings, and other technical aspects.

- **Part Replacements:** Ensuring that replacement parts are compatible with existing systems and meet regulatory standards
- **Discontinuance and Obsolescence:** Support smooth product discontinuation and develop obsolescence management strategies ensuring functional and regulatory requirements.
- **Design Change Control:** We implement robust design change control processes to ensure that all changes are properly documented, evaluated, and approved.

PRODUCT SECURITY GAP ASSESSMENT

Our services help ensure that medical devices are secure, compliant, and protected against potential cybersecurity threats. Implement security enhancements in line with FDA Cybersecurity Guidelines, EU MDR, and IEC 62304.

CAPA AND RCA ACTIVITIES

- Investigate quality issues, device failures, and audit findings using Root Cause Analysis (RCA) methodologies.
- Implement CAPA strategies to eliminate defects, enhance design reliability, and prevent recurrence of compliance issues.
- Maintain CAPA records to support regulatory inspections and quality audits.

REACH AND ROHS MANAGEMENT

- Ensure compliance with REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) and RoHS (Restriction of Hazardous Substances) to meet environmental and safety regulations.
- Identify and eliminate hazardous substances in materials while maintaining product integrity.

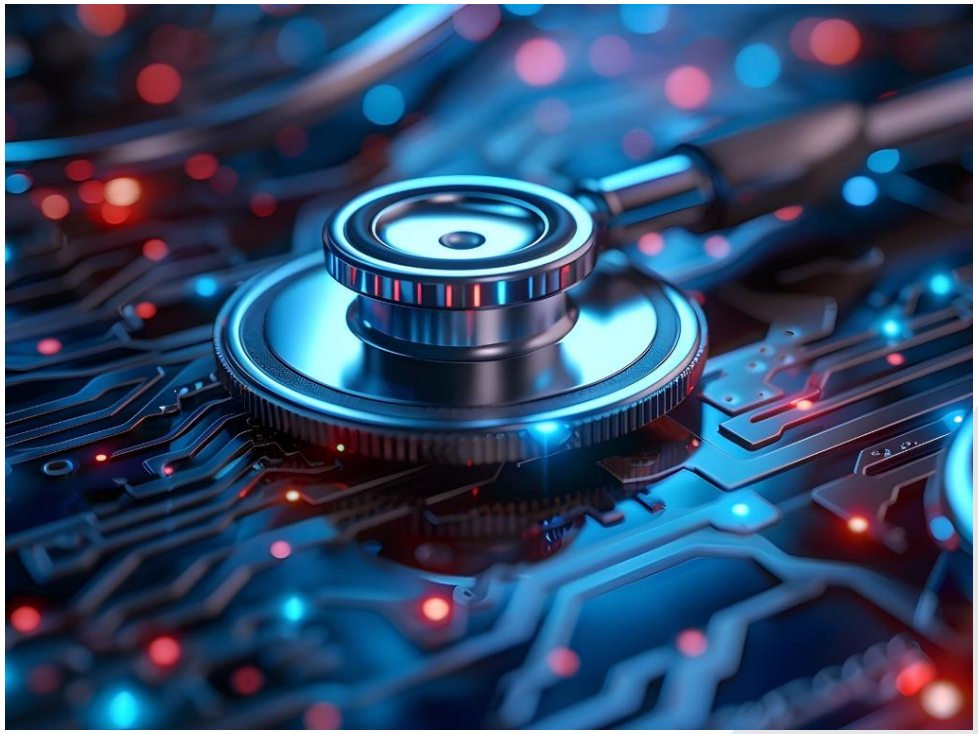
RELIABILITY AND ENVIRONMENTAL TESTING

- Environmental stress testing (temperature, humidity, vibration).
- Reliability testing (HALT, HASS).
- Durability testing (mechanical stress, wear).
- Failure analysis.

FIRMWARE DEVELOPMENT

We specialize in developing robust, efficient, and reliable firmware for a wide range of embedded systems.

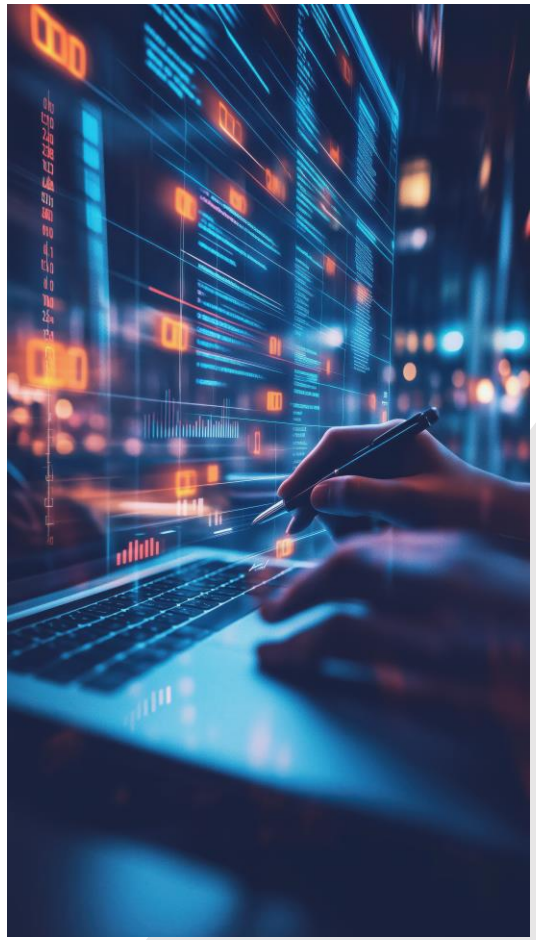
- **C/C++, Embedded Linux, RTOS:** We leverage the power and flexibility of C/C++ to create high-performance firmware tailored to specific hardware requirements. For more complex embedded systems, we utilize Embedded Linux, providing a powerful and versatile operating environment. For applications demanding precise timing, we employ Real-Time Operating Systems (RTOS).
- **Peripheral device drivers:** We develop efficient, communication protocols ensuring seamless peripheral integration across embedded systems including:
  - SPI (Serial Peripheral Interface), I2C (Inter-Integrated Circuit), UART (Universal Asynchronous Receiver-Transmitter), USB (Universal Serial Bus), Wi-Fi, BLE (Bluetooth Low Energy)
  - Multiple Device Architecture: Developing scalable and interoperable architectures that support multiple devices, ensuring efficient interaction and compliance with regulatory standards.



SOFTWARE DEVELOPMENT

- **Desktop, Web, Cloud:** We develop secure and scalable software applications for desktop, web, and cloud platforms, adhering to HIPAA regulations for patient data protection.
- **Re-engineering / Modernization:** We modernize legacy systems, ensuring compatibility with current technologies and regulatory standards. This includes updating outdated software and hardware, improving performance, and enhancing security, extending the life and capability of valuable medical device systems.
- **Mobile Apps:** We create intuitive and user-friendly mobile applications (native and hybrid) for healthcare companies, enabling remote patient monitoring, data access, and device control.
- Power BI based Dashboards/Reports: We develop interactive Power BI dashboards and reports, providing real-time data visualization and analysis for medical device performance and patient outcomes
- **Integrations with EMR and EHR:** We specialize in integrating medical device software with Electronic Medical Records (EMR) and Electronic Health Records (EHR) systems to ensure seamless data exchange, improved interoperability, and enhanced clinical workflows.
- **Standalone to Enterprise:** We scale medical device software from standalone applications to enterprise-level solutions, accommodating growing data volumes and user demands.
- **Software Testing:** We provide rigorous software testing services, ensuring the safety, reliability, and performance of your medical device applications including:

  Functional | Performance | Reliability | Security



AUDIOLOGIST (SME) SUPPORTING ALL TEAMS

Clinical expertise integrated into every phase.

We provide dedicated Audiologist Subject Matter Expert (SME) support, ensuring clinical accuracy and patient-centred design throughout your medical device development process. Our Audiologist SME acts as a vital resource for all teams, bridging the gap between technical development and real-world clinical application. These services help ensure that medical devices meet high standards of audiological care and compliance, benefiting both the development teams and end-users.

EXPERTISE IN SYSTEMS ENGINEERING

- At Decos, we specialize in Systems Engineering to develop high-performance, compliant, and interoperable medical devices. Our expertise ensures seamless integration of hardware, software, and connectivity, meeting strict regulatory standards while optimizing reliability and usability.

- We are ISO 13485 certified company supporting all Class II & Class III activities for NPI's (New Product Implementation) and Remediation (FDA, MDD & EU-MDR), following ISO 13485, 14971 and IEC 62304.

SYSTEMS ENGINEERING SERVICES

- Risk Management
- Biocompatibility Services
- Human Factors Engineering (HFE) and Usability Services
- Labelling and IFU
- Packaging, Handling and Environmental Testing (PHET)
- V&V (Verification & Validation)

RISK MANAGEMENT

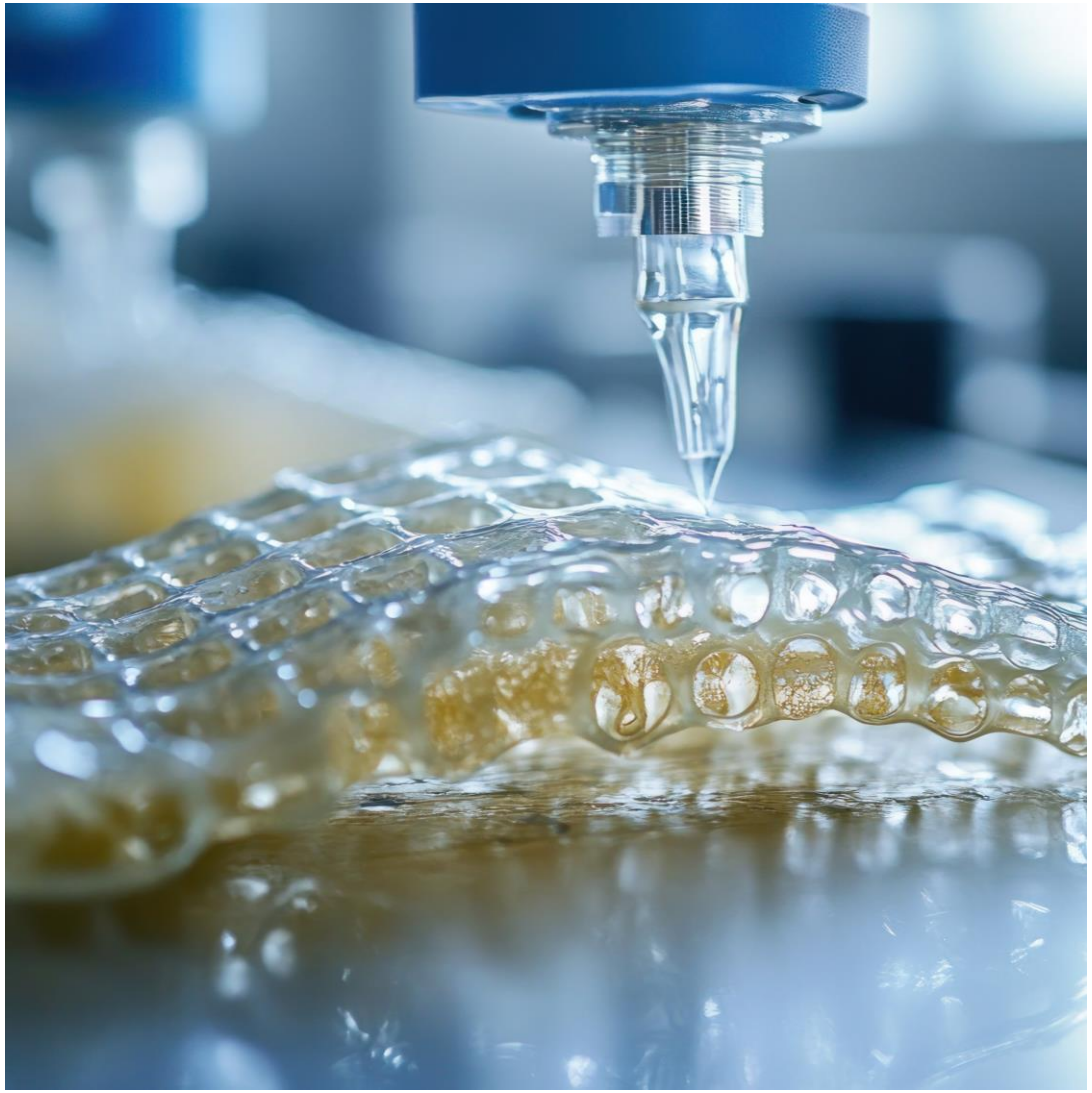
Risk Plan: We develop a tailored risk management plan that defines the scope, methodology, and responsibilities for risk assessment. This ensures a structured and comprehensive approach to identifying and managing potential hazards.

Risk Assessment: We conduct thorough risk assessments to ensure medical device safety and compliance. This includes hazard identification and analysis to detect potential risks in design, use, and environment. We evaluate severity and probability, implement risk control measures, and develop mitigation strategies to minimize residual risks and ensure regulatory compliance.

Risk Report and Risk-Benefit Analysis: We generate detailed risk reports that document the risk assessment process, findings, and mitigation strategies. We also conduct risk benefit analysis to demonstrate that the benefits of the device outweigh the residual risks, ensuring regulatory compliance and patient safety.

BIOCOMPATIBILITY SERVICES

- **Planning and Assessment:** Developing regulatory strategies and selecting necessary tests.
- **PFAS Compliance:** Screening materials for PFAS and ensuring regulatory compliance.
- **Literature Review**: Using existing data to reduce unnecessary testing.
- **Data Interpretation:** Coordinating with labs like Nelson Labs and Eurofins for compliance.
- **QMS Update**: Aligning Quality Management Systems with biocompatibility requirements.
- **Report Preparation:** Compiling comprehensive testing reports for regulatory submission.
- **Latex Evaluation:** Assessing allergen risks in latex-containing devices.



HUMAN FACTORS ENGINEERING & USABILITY SERVICES

We provide Human Factors Engineering (HFE) and usability services to ensure your medical devices are safe, effective, and user-friendly.

- **Use Specification Development:** Defining user profiles, intended use, and operational conditions.
- **Task Analysis:** Mapping workflows and identifying potential user errors.
- **Usability Engineering and Risk Management:** Assessing and optimizing design for usability.
- **Formative Usability Testing:** Early-stage testing and feedback to refine designs.
- **Usability Validation:** Final compliance testing and real-world performance validation.

LABELLING AND IFU

We specialize in ensuring medical device labels and IFUs are accurate, compliant, and clear by developing tailored labelling solutions that enhance safety and usability. We help companies meet global regulatory requirements, including FDA, MDR, and ISO standard. Our team mitigates risks by preventing labelling errors, managing the entire lifecycle of labelling documents, and ensuring compliance across international markets.

Our services include:

- UDI Management
- Labelling Requirements Update Standard
- Label Cleaning, Verification & Validation
- Supporting Translation Activities

PACKAGING, HANDLING AND ENVIRONMENTAL TESTING (PHET)

- **PHET Plan:** Testing devices for altitude, temperature, shock, vibration, and humidity endurance.
- **Functional Testing and Execution:** Simulating real-world conditions to ensure reliability.
- **PHET Report:** Comprehensive documentation of environmental testing results.

V&V (VERIFICATION & VALIDATION)

We develop detailed design verification plans, protocols, and reports to demonstrate that the device's design outputs meet the design inputs.

- **Design Verification:** We develop thorough design validation plans, protocols, and reports to demonstrate that the device meets its intended use and user needs.
- **Design Validation:** Confirming the device fulfils user needs and intended use.
- **Plans, Protocols and Reports:** Detailed documentation for regulatory compliance.

HOW CAN WE HELP?

From first concept to regulatory approval, Decos is your strategic partner in bringing safe, reliable, and innovative medical devices to life. With a deep bench of expertise across embedded systems, software, hardware, and compliance, we simplify the complexity of product development; so, you can focus on what matters most: improving patient outcomes.

Ready to transform your next medical device idea into a market-ready, compliant solution?

Let's talk. Book a free consultation today.

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