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Full service medical device contract manufacturer

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MEDI'NOV CONNECTION 2020

MDR – How contract manufacturers can help medical device manufacturers ensure compliance with the new regulation

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Summary

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- About Valtronic
- MDR – time frame, main changes & impacts on medical device OEMs
- MDR – the crucial role of contract manufacturers (CMs)
- What else can CMs do to help OEMs?
- More changes ahead?

Full Service Medical Device Contract Manufacturer

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Experience

35+ years

Medical Devices

>90% of our activity
ISO 13485 / FDA registered
Class I to III, incl. Active Implants

Expertise

Turnkey devices
Microelectronic assembly
Miniaturization

Full service

Design & Development
Industrialization & Manufacturing
Supply chain Management

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Key Figures

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1982
Creation

>350
Employees

3
Continents

+500
Medical devices

U.S.A.
Cleveland, Ohio
Design, Development, Industrialization & Manufacturing
Complex System Builds
Full Supply Chain Services

Morocco
Casablanca
Electronic Manufacturing Services
Manual Assembly
Volume Manufacturing

Switzerland
Geneva Lake Region
Headquarters
Design, Development, Industrialization & Manufacturing
Microtechnology Competence Center
Complex System Builds
Full Supply Chain Services

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Dedication to highest quality medical devices

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Neuromodulation

Cochlear implants
DBS implants & probes

Drug Delivery

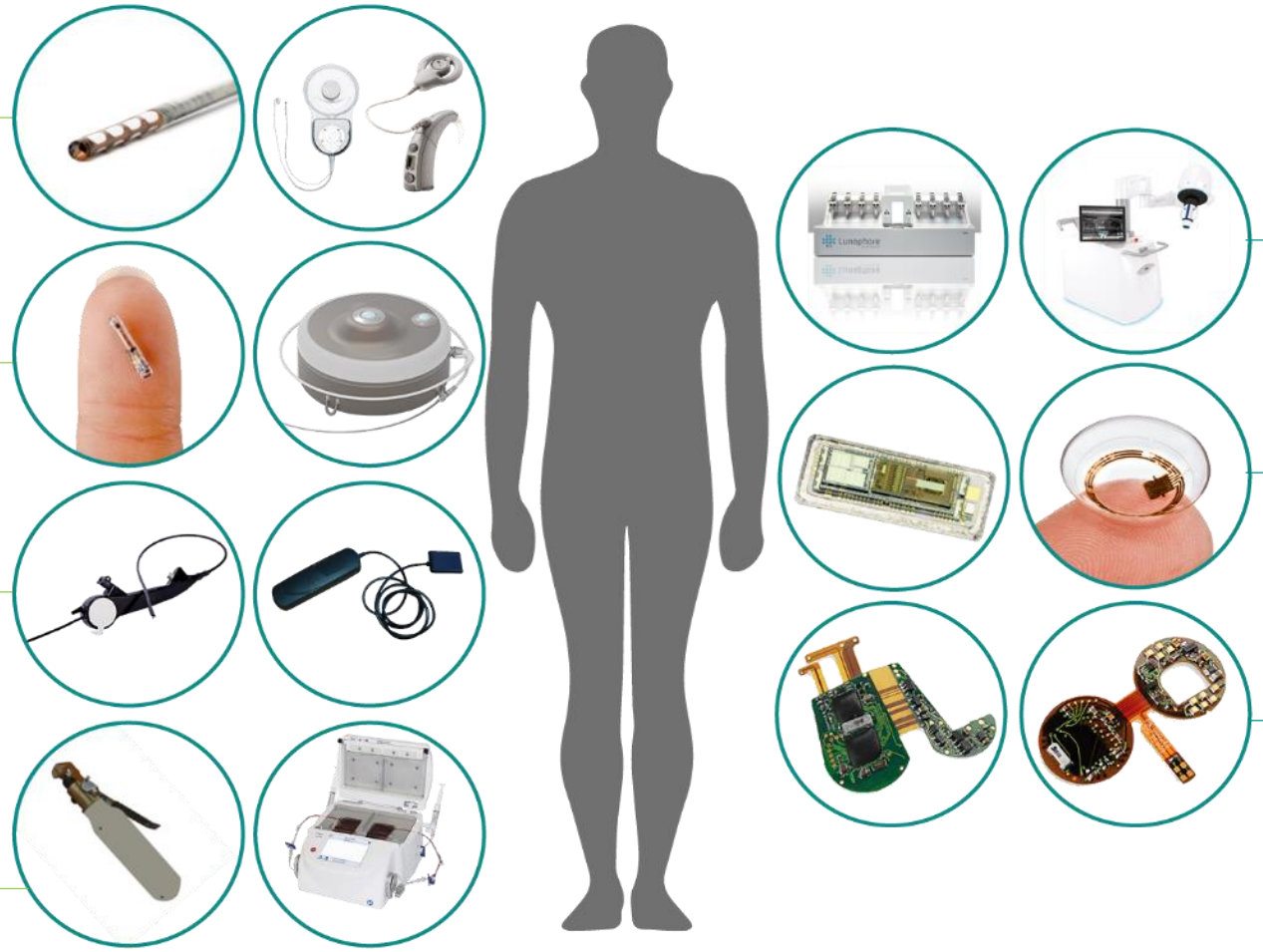
Glucometers & insulin pumps
Implantable morphine pumps

Imaging & Endoscopy

Disposable bronchoscopes
Dental X-Ray devices

Blood Processing, Urology & Renal

Tube sealers
Heater/cooling systems



Selection of applications

Turnkey Devices

Miniaturization

Microelectronic Assembly

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MDR - European Medical Device Regulation

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- Time frame:
  - Officially published on 5 May 2017 and came into effect on 25 May 2017.
  - Will replace the Medical Device Directive (MDD).
  - New rules will apply starting May 26, 2021 for MDR, and May 26, 2022 for IVDR .

- Objective:
  - Robust, transparent, predictable, and sustainable regulatory framework for a very high level of safety within the healthcare industry.

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MDR / Main changes

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- More products will be considered as Medical Devices, such as:
  - Colored contact lenses and cosmetic implants
  - Devices for “prediction and prognosis” of a disease
- Unique device identification (UDI)
  - European Databank on Medical Devices (Eudamed)
- Rigorous post-market oversight
  - Unannounced audits, along with product sample checks and product testing
- More rigorous clinical evidence for Class III and implantable medical devices
- Systematic clinical evaluation of Class IIa and Class IIb medical devices
- No “grandfathering” provisions
  - All currently approved devices must be recertified in accordance with the new requirement

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Impact on OEMs & the European medical device market

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Product portfolio review

- Certification processes for new products
- Recertification of products already on the market

Longer time to market

- More devices will require certification
- Elevated clinical testing requirements
- Increased demand on notified bodies

Investment of time & money

- Thorough QMS
- Review and adaptation of documents & processes
- More technical files to support certification

Unannounced audits for critical suppliers

- Higher requirements on supplier selection and control

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Contract manufacturers - Crucial for compliance

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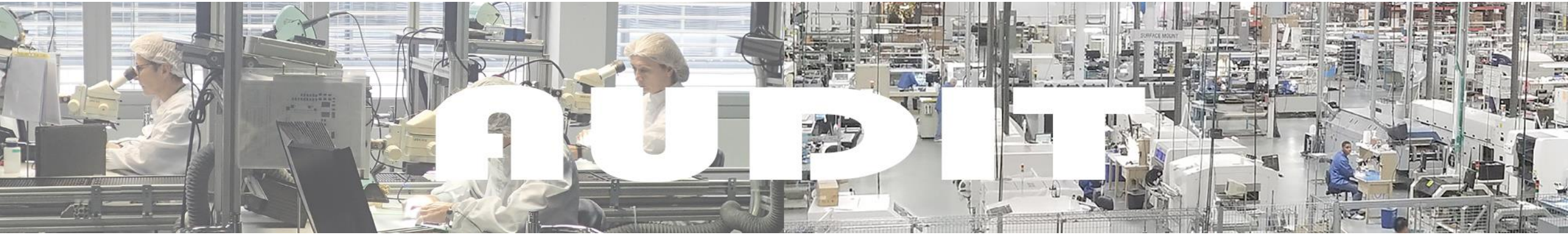
- Supplier is “Critical” when involved in device design, manufacturing, inspection or testing
  - Often the case for electronic contract manufacturers

- Critical for your product certification, why?
  - Must be well prepared for unannounced audits:
    - Non-conformity will be raised against the manufacturer, not the supplier
    - Non-compliance, non-conformities will delay your production and certification
    - Risk to further increase time to market
    - Risk for your supply continuity



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Contract manufacturers – Make the right choice

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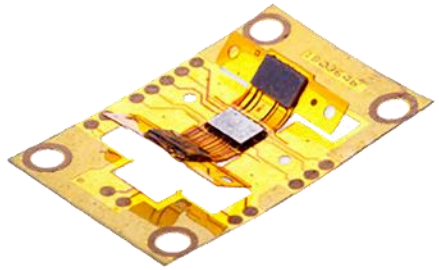
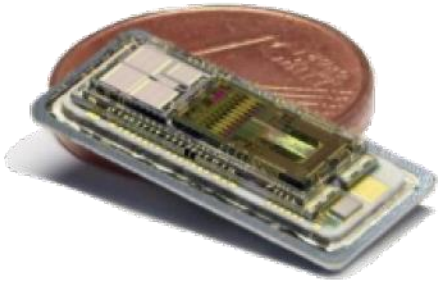
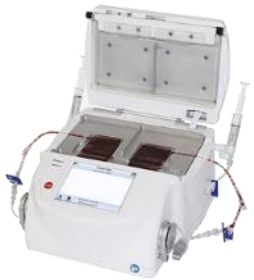
- When choosing an electronic contract manufacturer, check for:
  - ISO 13485:2016 certification - Thorough QMS in place
  - Experience in various medical devices – Detailed technical documentation
  - Experience in active implants – Highest traceability
  - Quality culture - Medical devices of highest quality

- Experience with customer & notified body audits
  - Team ready rapidly
  - Quick access to required documents

➢ Look for a contract manufacturer who will address both : regulatory and quality concerns

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What else can your CM do for you?

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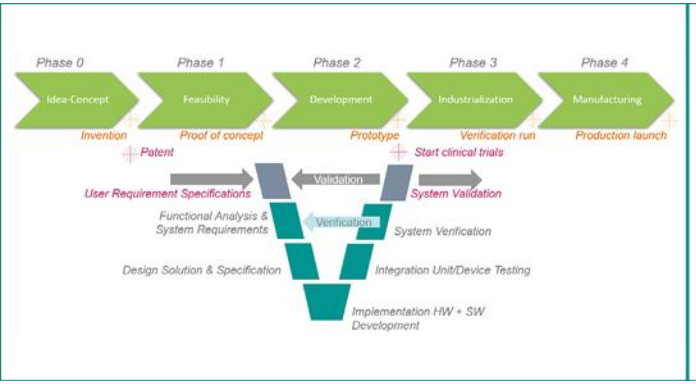
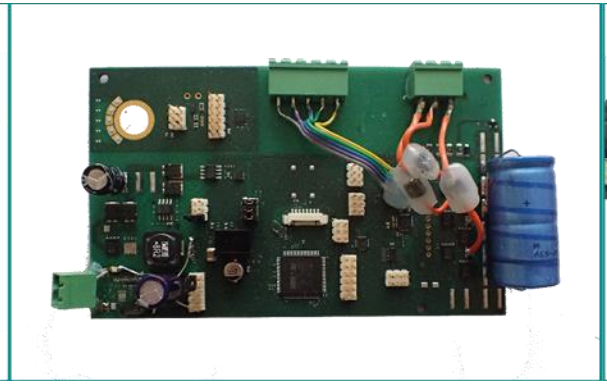
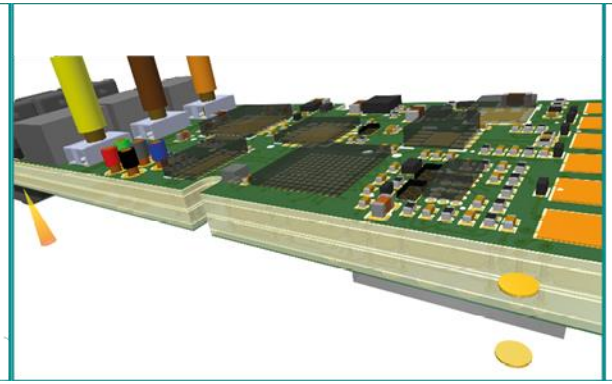
Optimize time to market with efficiency at every project step

- Design & Development with Manufacturing in mind (DFM)
  - Risks assessed together
  - BOMs elaborated with qualified suppliers
  - Manufacturing constraints taken into consideration to avoid iterations
  - Customized test strategy
  - Optimized flow for highest quality, and respect of cost and deadlines
  - Support in product adaptation to meet new MDR requirements







What else can your CM do for you?

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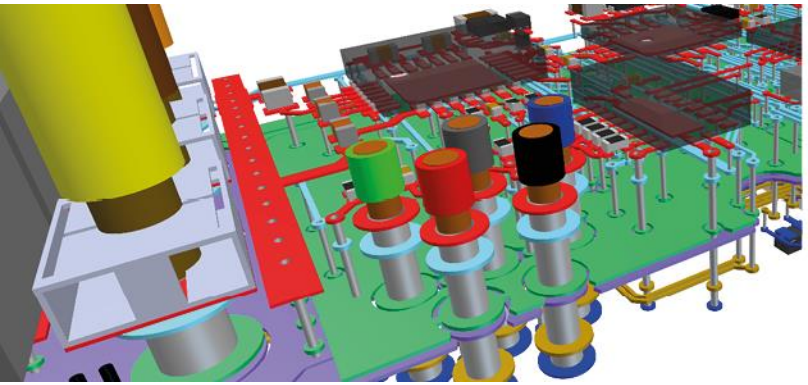
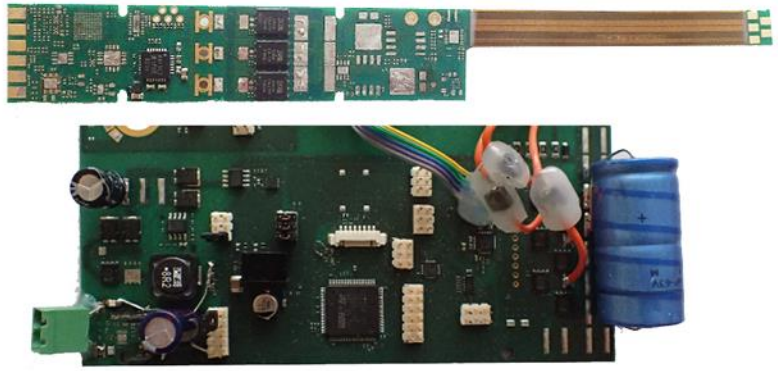
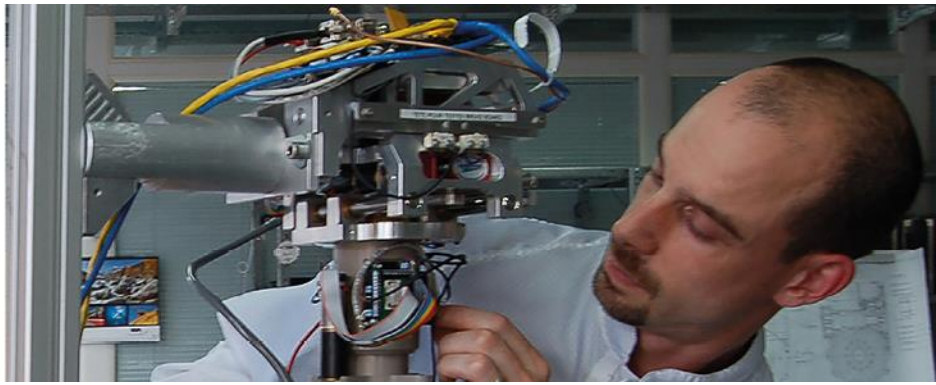
Optimize time to market with efficiency at every project step

- Prototypes as close as possible to final product
  - Early prototypes for critical functions testing
  - Fast pre-series prototyping matching product specifications
  - Prototypes realized on real production lines
  - Prototypes delivered with thorough documentation
  - Close to final product which allows for earlier start of clinical trials







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What else can your CM do for you?

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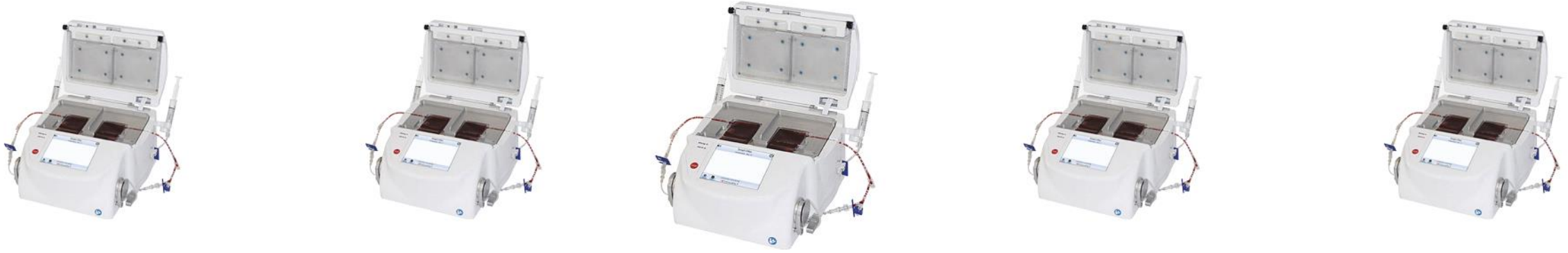
Optimize time to market with efficiency at every project step

- Industrialization and Manufacturing
  - New Product Introduction (NPI) – Leave nothing to fate when taking on new projects
  - Processes & checklists to collect thorough product information
  - Open dialogue for identification of potential issues
  - Quick production ramp-up
  - For production transfers – Team sent to customer site to understand manufacturing steps



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What else can your CM do for you?

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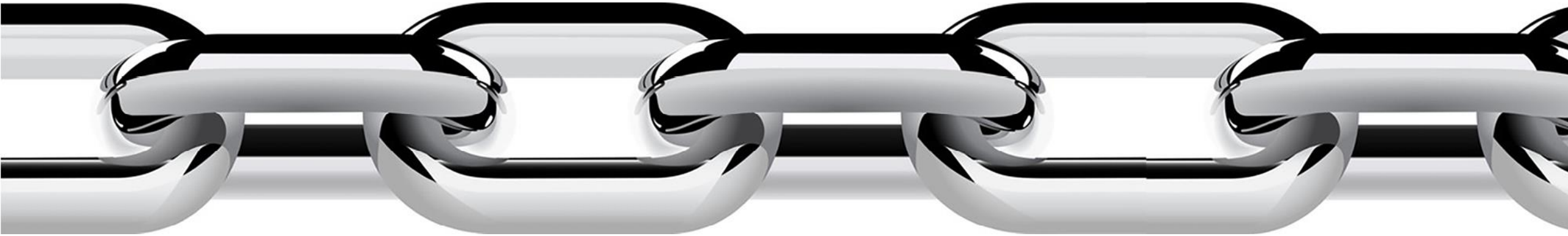
Optimize time to market with efficiency at every project step

- Full supply chain management
  - Sourcing already thought in engineering phase
  - Experience with large BOMs
  - Component life cycle analysis, Management of obsolescence & material shortage
  - Cost saving initiatives

SAP/MRP | Kan-Ban Methodology | QMS supplier approval | DMSMS and obsolescence management process



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Medical device market – Ready for the changes ahead?

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- MDR in May 2021 / IVDR in May 2022

- FDA is considering ISO 13485 to replace FDA Quality System Regulations (QSR)
  - So choosing an ISO 13485 certified contract manufacturer can be an asset to enter the US market

➢ New regulations are challenging but :
  - ➢ Safer products for patients
  - ➢ Opportunity for OEMs to gain competitive advantage on the medical device market

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To resume – Choose the right Contract Manufacturer

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Choose a partner who makes quality a priority and addresses both regulatory and quality concerns

- ISO 13485:2016 certified
- FDA registered
- MDSAP (Medical Device Single Audit Program) ready
- Long experience with medical devices
- Ready for unannounced notified body inspections
- Full-service provider
- Offering support at any stage of your project



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Full service medical device contract manufacturer

We are ready for the changes ahead

- Understanding of the medical device business
- Anticipation of our customers' needs
- One stop shop
- Highest quality
- Full product traceability

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