Francesco Malavasi

Director Device Management Cell & Gene Therapies

Contact

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www.linkedin.com/in/francesco-malavasi-1023475a/

Education

B. Eng. Management Engineering
GPA 101/110

Key Skills

Project Management
Product Management
Team leading
Budget Planning
Communication
Problem-solving

About Me

I'm currently Director for Device management at Bayer Pharmaceuticals, with 15 years of experience in developing medical devices and combination products. I'm also contributing, by leading organizational initiative, to increase efficiencies across our departments.

Experience

DECEMBER 2019- CURRENT JOB

Director Device Management Cell & Gene Therapies | Bayer AG and Bayer S.p.A (Berlin DE and Milan IT)

Main duties:

- Establish and lead the Legal Manufacturer entity for medical devices dedicated to CGT .
- Device Development product Leader for Cell and Gene Therapies dedicated devices, focused area: Central nervous system, and cardiovascular system.
    - Leading Design Input, Output, Design Verification and Design Validation activities
- Life-cycle manager for commercialized product, particularly focused on parenteral and reconstitution kits as:
    - Change management
    - Scale-up activities
    - PMS and PMCF support
    - Complaints investigation
- Project manager for design implementation, product design improvement and manufacturing technical transfers.
- Create and or supervise creation, update and transfer of DHF documentation, DMR implementation and transferring activities.
- Product representative for internal and external audit.
- Due diligence activity for production facilities and or

new product development
- Managing budgets up to 15 M €

MAY 2017- NOVEMBER 2019

Quality Manager Devices | Novartis (Holzkirche DE)

Main duties:

- QA project coordinator for all the combination products portfolio;
- QA project responsible for Development and commercialized products (parenteral+software);
- Responsible for Medical Device and combination product Risk Management, through proactive risk management tools and approaches, minimizing impact on global supplies and patients;
- Implement/harmonize/manage standard Risk Management System and tools for Development, Commercialization and Life Cycle Management of Medical Devices and combination products;
- Periodic risk management reporting for all Medical Device and Combination Products (according to ISO 14971);
- Product assessments, medical device reporting and recall activities per global standards and policies;
- Auditor for external and internal entities (Self inspection activities)

APRIL 2014- APRIL 2017

Device Development Manager | Sandoz -Novartis (Schaftenau AT)

Main duties:

- Create or supervise creation of device development documents, e.g. complete DHF, URS/design plan, risk assessments, qualification protocols, reports etc. according to Sandoz/Novartis and authority requirements (e.g. 21CFR820, 93/42/EEC) and Sandoz/Novartis requirements, quality plan;
- Leading Risk management activities, from the early planning to the transferring into commercial, including process related risk management;
- Leading Human Factor activities for the development of new drug delivery system according to the IEC 62366 , from the definition of the protocol, formative study, summative study and evaluation of the data collected;
- Maintenance of design control documentation for Medical Devices and Combination Product, including

risk management files for assigned projects;

- Device transfer to Production: Initiate on time transition to Production for successful launch and commercial manufacturing (assembly and testing) and related documentation (validation activities included);
- Participate as representative of Sandoz Biopharmaceuticals drug product and device development in assigned 'device' projects running in collaboration with Novartis Pharma or/and other Divisions as well as within Sandoz;
- Contribute to decision making that impacts goals, objectives, and strategies; actively contribute to resource allocation;
- Create, ensure implementation, and monitor progress of the respective development plans and especially of documentation status for assigned projects.
- and regulatory documents according to established processes for assigned device projects;
- Timely, reliable, and accurate information / communication about project specific issues within line function/management and to key stake holders/project teams;
- Best partners for device development and related documentation selected and strong relationships built to them;
- Development programs set up with partners (incl. contracts, QA agreements, processes, and governance) and tightly managed;

OCTOBER 2009- MARCH 2014

Quality and Regulatory affairs manager | Physion S.r.l. (Mirandola IT)

Main duties:

- Quality Manager for Physion. Responsible for creating, designing and implementing the current Quality System (ISO 9001, ISO 13485), trough quality manual, procedures and instructions
- Inner and supplier Auditor;
- Leader for the Physion's team during Audits performed by National Authorities and or Notified Bodies
- Complaint manager, investigation on field also, CAPA manager;
- Ensuring a constant monitoring of factory trend above customer satisfaction (post market surveillance)
- Create Quality agreement between customers and suppliers;
- Regulatory Affairs manager for Europe and Canada. Direct contact with notified bodies (European IMQ, Canadian SAI Global) continuous contacts with European countries and Canadian Ministry of Health

to ensure that all our medical devices are in comply with all regulation for medical device, during the project development and medical device life time.

- Regular updating to the R&D department about amendment or new regulations.
- Prepare technical files for the medical devices manufactured by Physion, according to European and Canadian Medical device regulations, and all the documentation related to be undisposed to National Authority or Notified Bodies.
- Collaborate like consultant, for another Company (Physion 's costumer), for preparing and submitting Class III MD (implantable)
- Member of the Risk team management, according to ISO 14971. During the project development, ensure to comply the regulations and assure that the medical device will be safe and according to European and Canadian laws for clinical trials and premarket approvals.
- Constant monitoring and updating all technical department for new rules, regulations or guidelines
- Determinate and plan sterilization operations (EO and Beta Ray) for Physion's medical devices

- Safety manager (according to Italian safety law)

PROFESSIONAL CERTIFICATIONS

- APMI E CONFINDUSTRIA: R.S.P.P. training course
- ISO 9001 at TÜV Akkademie
- ISO 13485 at TÜV Akkademie
- EN IEC 62304 at TÜV Akkademie
- ISO 14971 UNI/IMQ
- Supplier and internal quality Auditor at IMQ Milano
- Sterilization in outsourcing process management at TÜV Akkademie
- Canadian regulation for Medical Devices at TÜV Akkademie
- European Medical Device Regulation (MDR EU 2017/745)- Confinis (Switzerland)
- Japan PAL+ JMDL (Yaku Ji Hou) at Bellingswood Akademie (Switzerland)
- IEC 62366 and ANSI/HE 75:2010 Human Factor for Medical Device at AAMI (London UK)
- IEC 62304 and IEC 82604 Software Development Processes for Medical Devices and Combination Products at SQalE

Languages

ENGLISH – Business knowledge writing, reading and speaking (C1)
ITALIAN – Mother tongue
GERMAN – Medium level knowledge (A2 level)

References

Available upon request.

Francesco Malavasi

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