CVO-EUROPE.COM

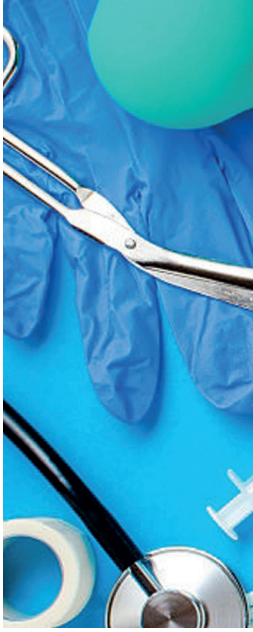
MEDICAL DEVICES

NEW MEDICAL DEVICE REGULATIONS & ISO 13 485

(UE) 2017 / 745
(UE) 2017 / 746
ISO 13 485:2016
MDSAP

CVO-EUROPE
LIFE SCIENCES CONSULTANCY

Due to the current regulatory and legal context, coupled with the constant pressure of competition, today's medical device manufacturers must constantly seek to increase the level of conformity of both their products and their quality management system.



ASSESSMENT/AUDITING

Our audit center offers you:

+ An assessment with an analysis of the gaps in all or part of your system between past, current and future requirements, accompanied by a remediation plan.
+ An audit of your system in accordance with new regulations including an audit and observation report.

These two services can be extended to all your suppliers and/or service providers.

SCOPE:

+ UE 2017/745 and 2017/746
+ ISO 13485:2016
+ ISO 80002-2
+ ISO 62304 et ISO 80002-1
+ ISO 14971
+ MDSAP
+ 21 CFR 820

TRAINING

Our training offer includes:

+ European Medical Device Regulation - 2017/745 & 2017/46 (QR271).
+ MD and MD DIV technical documentation (QR272).
+ QMS – Medical Devices in Europe (QR280).
+ Developments to ISO 13485:2016 (QR281).
+ ISO 14971:2013 Risk management for medical devices (GR410).
+ Medical Device Single Audit Program – MDSAP (QR340).
+ US (FDA) Medical Device Regulation (QR270).
+ E-learning module: GMP for Medical Devices (EL_QR130_MO_DM).

The above training courses can be customized to meet your specific needs, depending on the gaps identified after the assessment (practical cases and customized examples). These training courses can be conducted on site or remotely (virtual classes).

REGULATORY SCOPE:

EU REGULATIONS 2017/745 AND 2017/746
ISO 13485
ISO 80002-1 / ISO 62304
ISO 80002-2
ISO 14971
MDSAP
21 CFR 820

COACHING

With our coaching service, we can accompany you in the:

- Transition from 93/42 to Regulation 2017/745.
- Transition from 98/79 to Regulation 2017/746.
- Design of an improvement and upgrading plan for your QMS (Quality Management System).
- Design of an implementation plan for Post-Market Clinical Surveillance.
- Analysis of differences in registration practices outside Europe (USA, Canada, Brazil, Japan, Australia).
- Validation strategy for your QMS software (in line with ISO 80002-2:2017 requirements).
- Validation strategy for your Medical Device software (in line with ISO 62304 and ISO 80002-1 requirements).
- Comprehensive risk management strategy (ISO 14971 v2012 and additional requirements for new regulations including IEC/TR 80002-1 Medical Device software).
- Updating your risk management.

IMPLEMENTATION

Depending on your level of expertise and the availability of your teams, we work with you in:

- Improving and upgrading your QMS (in line with ISO 13485 v2016 requirements, 21CFR820).
- Upgrading your technical & regulatory files, DHF, DMR, CE Marking, 510k, RMP...
- Quality assurance, quality system management, audit support (NB, customers...).
- MD Engineering: PMO, URS, Design reviews, MEDDEV, functional & technical analysis, Experts.
- Design and development of software (in line with IEC62304, IEC 82304).
- Support to preclinical & clinical development.
- Verification of your Medical Device software (in line with ISO 14971 & ISO 80002-1, FMEA requirements) & validation (Biocompatibility ISO 10993...).
- Qualification & validation of system, equipment, process, methods (analytical, cleaning, sterilization, packaging, UDI...), metrology, calibration.
- Validating your systems for the QMS (in line with ISO14971, ISO 80002-2 requirements).
- Securing and/or computerization of processes for better data control & Data Integrity requirements.
- Implementating comprehensive risk management (ISO 14971 v2012 and additional requirements for new regulations including IEC/TR 80002-1 Medical Device software).

Focus on your core business and trust the compliance leader for your regulatory concerns!

1. EUROPEAN REGULATORY COMPLIANCE EXPERTS

A pioneer in validation in the life sciences since 1995, we have developed true expertise in regulatory compliance, as well as a relationship of trust with the main players in the pharmaceutical, cosmetics and medical device industries.

Our expert knowledge of the strong regulatory constraints of the pharmaceutical industry enables us to better understand the new requirements that are gradually being imposed on medical device manufacturers.

2. A COMPLETE AND CUSTOMIZED OFFER

We have the necessary know-how and the teams to meet all your needs, taking into account your economic and organizational constraints: consulting, audit, training, projects and technical assistance. You thus benefit from our high level of expertise offering you customized solutions.

3. TWO-FOLD EXPERTISE

All of our employees are specialized in life sciences and have expertise both in business (R&D, production, logistics, laboratory, quality, IT, HSE) and regulations.

4. A MULTIDISCIPLINARY TEAM

The strength of our group is based on our multidisciplinary team with rich and varied profiles and experience: pharmacists, engineers, technicians, doctors and masters in engineering, computer science, chemistry and biotech, from junior to expert level.

5. THE TOOLS TO SUCCESS

We invest in a strategy to capitalize on our know-how (methodologies, regulatory monitoring tools, GxpManager «Agile Compliance» software tool, etc.). Our service provides you with the tools to allow you to experience unequalled productivity gains.

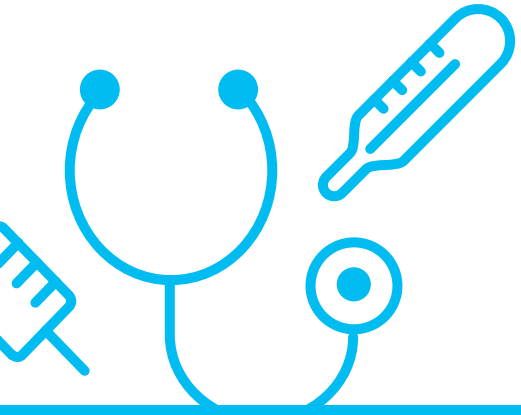
6. ONGOING TRAINING

Our internal training center enables us to maintain and continuously develop the level of skills of all our employees. In concrete terms, each year we invest 7% of our payroll in internal training.

CVO-EUROPE

Since 1995, CVO-EUROPE's multidisciplinary team has been supporting life science companies at every stage (design, validation, operation, digital transformation) of critical activities that may affect product quality, data integrity and patient health, whilst ensuring the compliance of their systems, equipment, processes and data.

With its comprehensive service range (consulting, shared service center, auditing, and instructional engineering), the CVO-EUROPE Group is committed to bringing its clients effective and innovative solutions whilst staying true to the human values that have characterized it from the outset.



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