CSVapt®

IT-TESTING.de®

adapted

precise

tailormade

SEEING AND UNDERSTANDING COMPUTERIZED SYSTEM VALIDATION IN A WHOLE NEW WAY!

- **CSV*apt*®** as an accepted and natural part of your company!
- **CSV*apt*®** as a daily companion for your workforce!
- **CSV*apt*®** as a natural, accompanying partner for your service providers!

WE ACCOMPANY YOUR ORGANIZATION ON THE WAY TO SECURE CSV IMPLEMENTATION :

***A*dapted**:

- The regulated organization is at the core to ensure patient safety, product quality and data integrity.
- Management will commit to the requirements of the regulated industry.
- The employees will understand and implement the working world and the working methods of the regulated industry.
- The service providers will see themselves as extended workbench of the regulated company and will act accordingly.

***P*recise**:

- The computerized systems and processes are validated exactly as it will be required based on risk and must be questioned with critical thinking.
- The work instructions and process descriptions are formulated precisely and are aimed at the currently regulatory purpose.
- Coordinated forms contain exactly the information required for the regulatory work environment.
- The process interfaces to the external and internal service providers are precisely defined.
- The specifications for the interfaces are implemented in a targeted manner and the functionality of the interfaces is set up.

***T*ailormade**:

- The scope of the documentation is managed according to the regulatory requirements.
- The service providers are accurately selected and qualified according to the regulatory purpose.
- The employees are appropriately prepared for the relevant audits.
- The internal CSV team is trained according to the requirements in a targeted and appropriate manner.
- The management receives appropriate rules for the control and traceability of the implemented measures.

Heaven can wait.

But: Validation can’t wait!

CSV*apt*®

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Your contact person:
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CSV | GxP | Compliance | QM
Software testing | Audits
Validation of medical devices

IT-Testing.de® | Carl-Zeiss-Straße 45 | D-55129 Mainz | Germany | Tel.: +49 6131 49 56 981 | https://IT-Testing.de

EC REP

European Authorized Representative

EC REP – OUR TASKS TO SERVE MEDICAL DEVICE (MD) MANUFACTURER

Full e-service for your company

to ensure the regulation requirements of the European Economic Area

EC REPRESENTATIVE: EC REP – INITIAL TASKS – CHECK THE CONFORMITY OF

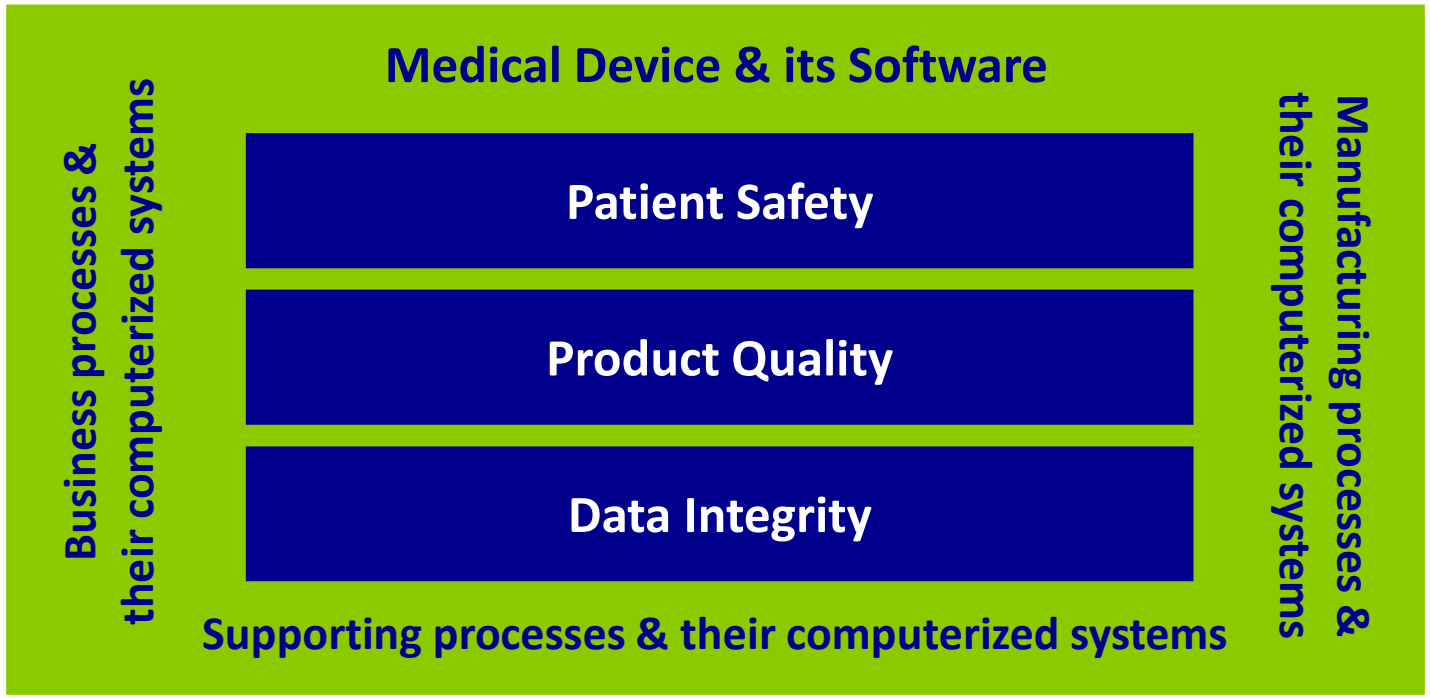
- the **Quality Management System** (QMS) according to ISO 13485
- the **Risk Management System** (RMS) according to ISO 14971
- the **MD software** regarding software lifecycle processes according to IEC 62304, if necessary
- the **health software** according to IEC 82304, if necessary
- all related processes and **computerized systems** for **validation** purposes: **CSV**

7 Steps For Registration a MD for the European Market

1. Exercise of the mandate as EC Representative (EC REP) by Dipl.-Ing. Thomas W. Hoehle, engineering company IT-Testing.de®, according to EU Regulation 2017/475 (**MDR**) for a specific Medical Device (MD) and to EU Regulation 2017/746 (**IVDR**) for a specific In Vitro Diagnostic Device (IVD) for an unlimited period of time.
2. The **mandate as EC REP** is given in writing by MD manufacturer. The acceptance of the mandate is also confirmed in writing by Dipl.-Ing. Thomas W. Hoehle.
3. The EC REP takes over the registration of the MD at the **BfArM** (Bundesinstitut für Arzneimittel und Medizinprodukte) and in **EURAMED**, so it can be used in studies promptly.
4. Complementary to 2. the EC REP participates in the corresponding modification of the **GTC** (General Terms and Conditions) and the **data protection regulations** for Germany and for the EU.
5. The EC REP finalizes the already prepared **DiGA application** and submits it.
6. If an **EU declaration of conformity** for the MD is not yet available, the EC REP will take the lead in obtaining one for MD manufacturer. If an EU declaration of conformity is available, the EC REP checks it and submits it.
7. The EC REP **reviews the technical documentation** of the MD and supports the modification according to the requirements of the MDR of the EU, if necessary.

EC REPRESENTATIVE: EC REP – PERMANENT TASKS

- Permanent quality checks using manufacturer's **QMS** & **RMS**
- Regular **audits** of the manufacturer and its service providers and suppliers



EC REP

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