ADEODATA
Life Science Validation

COMPANY PROFILE

Validation for Life Science

THE TEAM

The whole Adeodata team.

***Adeodata Day**, January 2019*

SECTION 1
FACTS & FIGURES

An overview on history and numbers of the company

GENERAL INFORMATION

- Founded in 2001.
- Two legal entities:
  - ADEODATA SA, Lugano CH;
  - ADEODATA S.r.l., Milano IT.
- Employs about 60 people, 50 of which are professionals, 3 administratives and one IT.
- It uses 4 external specialised professionals.
- From 2017 we are present in Parma.
- From 2018 we are present in Padua (close to Venice) and Pomezia (close to Rome).

CERTIFICATIONS

Adeodata has a quality system certified under ISO 9001:2015 for:

- Planning and implementation of consultancy services
- Validation of computerized systems
- Compliance checks of computerized systems in GxP scope
- Calibration of measuring devices, instruments, loops
- Validations and thermal mappings
- Environmental classification and monitoring
- Analytical and predictive infrared thermal imaging

SECTION 2
QUALIFICATIONS & CALIBRATIONS

An overview of the qualification and calibration services that Adeodata can provide to its customers

QUALIFICATIONS: SKILLS

Adeodata operates according to national and international regulations and guidelines, for example:

- EU **GMP**, Annex 11 & 15, **FDA** and ICH guidelines
- UNI EN **ISO** 14644-1 / 2/3/4/5/7
- **WHO** Technical Report Series, No. 961, 2011 Supplement 8, Temperature mapping of storage areas (2015)
- **EN 14175** - Suction hoods
- **EN 12469** - Biotechnology - Performance criteria for microbiological safety cabinets (2000), - etc.
- **Agalloco** (Pharmaceutical Technology - Guide Line)
- **GAMP** Good Automated Manufacturing Practices

INSTRUMENT CALIBRATION

Adeodata provides calibration service for a wide range of physical quantities.

Part 1

- Conductivity: from **0,06 µ S/cm**
- Pressure: from 10 up to 500 Pa (for rooms and hoods)
  up to 2.000 Pa (HVAC filters)
- Humidity: from 0 to 100% RH%
- Temperature: from **-80** to **700 °C**
- Air speed: up to15 m/s
- Linear speed: up to10 m/s
- Nr. of laps: up to 99.900 laps/min
- pH: 4-7-9 (certified sample solutions)

Part 2

- Flow: up to 34.000 l/h (ultrasound)
  or up to 2.800 kg/h (mass)
- Vacuum: from **10^{-6} bar**
- Pressure: up to **600 bar**

Radiometric measurements (pass boxes, photo stability cameras, ...)

- UVA: up to 50 W/m^2
- UVB: up to 30 W/m^2
- UVC: up to 1,5 W/m^2
- Lux: up to 4000 lux

QUALIFICATIONS

During the validation, Adeodata is able to meet the following requirements:

- Risk analysis / impact assessment GMP - GxP
- Drafting and execution of documents such as

  VPL, URS, FS, DQ, FAT, SAT, IQ, OQ, PQ, VR, SOPs
- Support for Commissioning / Decommissioning

THERMAL QUALIFICATIONS

- Steam and dry heat sterilizers
- Depyrogenation oven
- Ovens
- Filtration skid
- Stoves - Muffles
- Tunnel - Instrument washer
- Lyophilizers

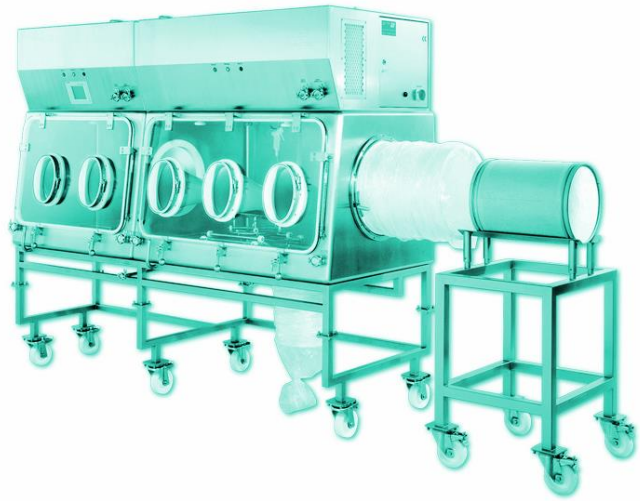
THERMAL DISTRIBUITION STUDIES

- Rooms of stability and photo-stability
- Climate chambers
- Fridge, freezer and cryostats
- Cold rooms, warm rooms
- Incubators
- Dryers
- Reactors

Feasibility studies for the installation of environmental monitoring systems for **warehouses** and environments dedicated to the storage of material and / or equipment.

QUALIFICATION OF ENVIRONMENTS AND EQUIPMENT WITH CONTROLLED CONTAMINATION

- HVAC systems - UTA - Cell Factory
- «LAF» unidirectional flow hoods
- Hoods / Down-Cross Systems
- Biohazard hoods
- Chemical Hoods
- Insulators - Glove Box - RABS



Adeodata also provides a service for starting and balancing HVAC systems.

SECTION 3
COMPUTERIZED SYSTEMS VALIDATION

An overview on the validation services that Adeodata can provide to its customers

SERVICES IN BRIEF

- Validation of computerised systems (ref. Annex 11 to EU GMP, FDA 21 CFR-11, Data Integrity guidelines)
  - From ERPs to PLCs
  - From HPLCs to EDMSs
  - From IT infrastructures to electronic spreadsheets
- Quality systems about computerized systems
  - Validation policies on computerised systems
  - Assessments and remediation plans/activities
  - Maintenance of the validation state on computerised systems
- Assessment on Data Integrity (Gap Analysis)
- Project Management
- Instrumental verification, equipment qualification, process systems and utilities qualification (ref. Annex 15 to EU GMP)

COMPUTERIZED SYSTEMS VALIDATION - CSV

Following ISPE GAMP 5 guidelines:

- Identification of process and user requirements
- Audit to SW and IT services providers
- Drafting of Validation Plan
- Drafting of Risk Analysis document
- Analysis of the SW provider documentation (FS, SDS, HDS)
- Drafting and execution of validation protocols (IQ, OQ, PQ)
- Drafting of Validation Report (and corrective actions)
- Drafting of SOPs for the maintenance of the validation state
- Training to the personnel involved in the validation activities
- Periodic reviews

MAIN ACTIVITIES

A brief overview of the systems we have validated till now, references available upon request.

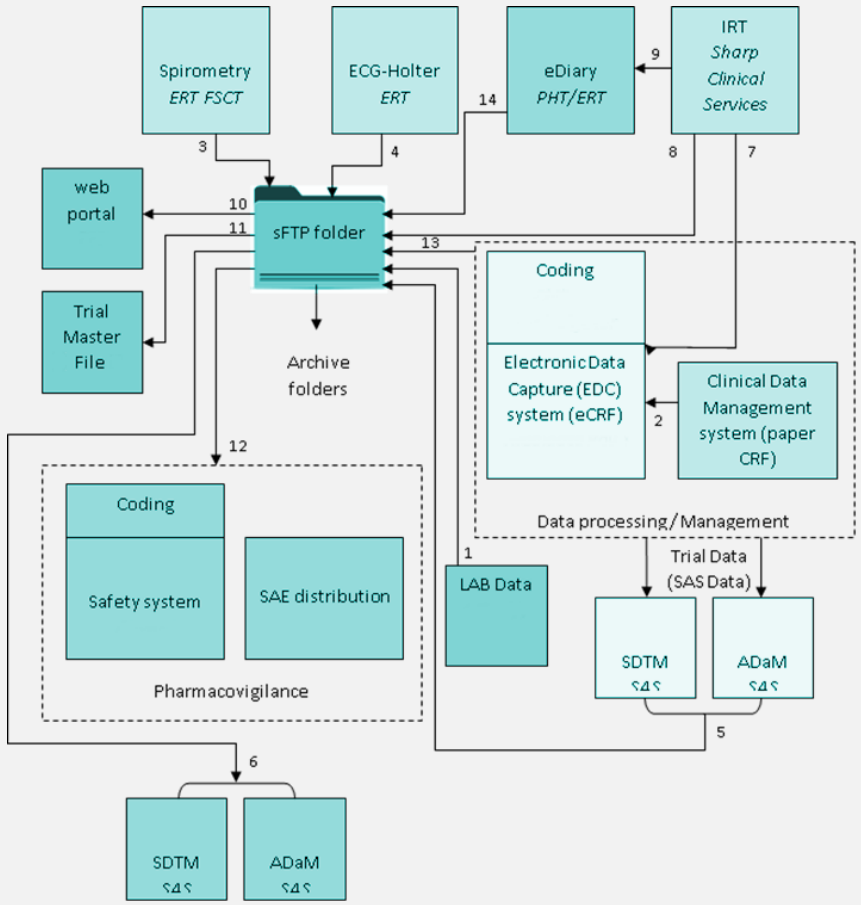
ERPs and EDMSs

- Several validation + upgrade and maintenance activities on SAP & SAP Hana
- Validation of Microsoft ERP systems (AX, Dynamics, Navision)
- Validation of vertically integrated pharmaceutical ERPs (Infor, Parcel, …)
- Validation of EDMSs like Trackwise, Documentum/LSS, Adipharma, …

Dedicated SWs and infrastructures

- Validation of SW for serialization, laboratories (LIMS, ELN, CDMS, ...), SW for IPC, dispensing, MES, DCS/SCADA, Pharmacovigilance, eTMF/ eSubmission, SW for calibration and maintenance management (CMMS) and several more
- Assessment (Data Integrity, Annex 11, 21 CFR part 11)
- IT infrastructure qualification
- Audit to external providers (SaaS, PaaS, …)

SPECIAL PROJECTS



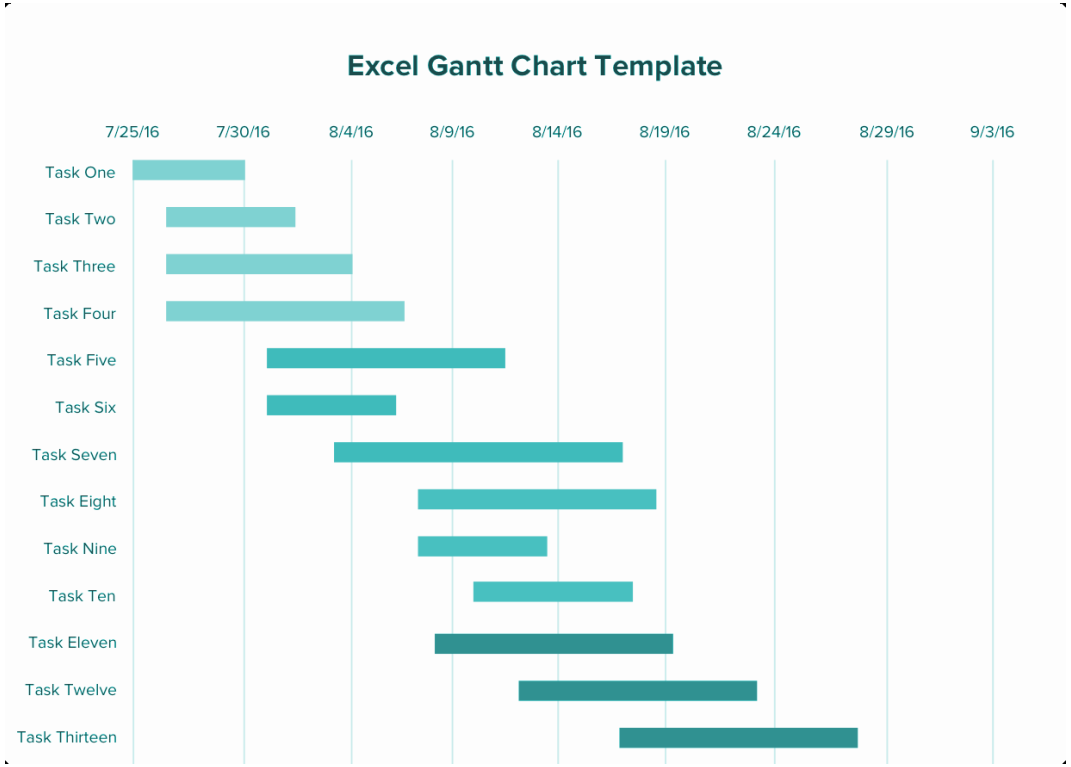
Analysis and mapping of the clinical data flow with the primary goal of evaluating the level of compliance of the systems in use with Part 11 rules.

- Identification of the computerized systems and interfaces involved in an eClinical Platform.
- Definition of the requirements of data integrity and the relevant preventive and corrective measures.
- Detection and mapping of the clinical data and information flow in a case study in order to illustrate the evaluation of the compliance to data integrity requirements.

PROJECT MANAGEMENT

Support to the set-up and management of complex validation projects:

- Set-up of the project plan (schedule, resources, cost)
- Management, control and update of projects' time and cost
- Support for the drafting of suppliers' contracts (products and services)
- Technical and economical comparison between suppliers proposals
- Software selection



SECTION 4 TRAINING ADVICE GXP AUDIT

Quality Systems services

QUALITY SYSTEMS SERVICES

- GxP seminars
- In-house courses (Quality Systems is able to assist you in the process of obtaining funding from inter-professional funds).
- Advice
  - Quality Systems has developed a series of services dedicated to GMP compliance to support companies in solving the most complex problems, such as:
    - GMP risk assessment
    - Reorganization of the Quality System processes
    - Drafting and revision of documentation and reports, SOP, VMP, PQR / PAR
    - Due diligence
    - Outside resourcing
    - Cleaning validation
    - Documentation translation
    - Drafting of registration dossiers in CTD format
    - Drafting of technical files for MD
- Audit / Mock Inspections, in preparation for authority inspections

QUALITY SYSTEMS
Training & Consulting

THANK YOU!

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