



COMPANY PROFILE

2024

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Since 2013, **QUALITY COMPLIANCE** was established with a view to become essential partner for industrial, service, and medical sectors such as pharmaceutical industries, medical examination laboratories, bioequivalence canters, veterinary industries, food industries, cosmetics, medical devices, and others.

ABOUT US

QUALITY COMPLIANCE , upgrades, and continually improves its performance that will be transferred to **QUALITY COMPLIANCE** customers for their benefit and improvement.

We are proud of continuously providing services to our partners to their entire satisfaction. Since our start-up, we have completed projects timely for CGMP Turn Key Projects, Storage systems / Transportation system Qualifications and host Training sessions on GMP/GDP requirements. . With a group of consultants located globally from varied expertise and backgrounds we have the capabilities to fulfil your needs with the best possible solution from conceptual design to the compliant operation.

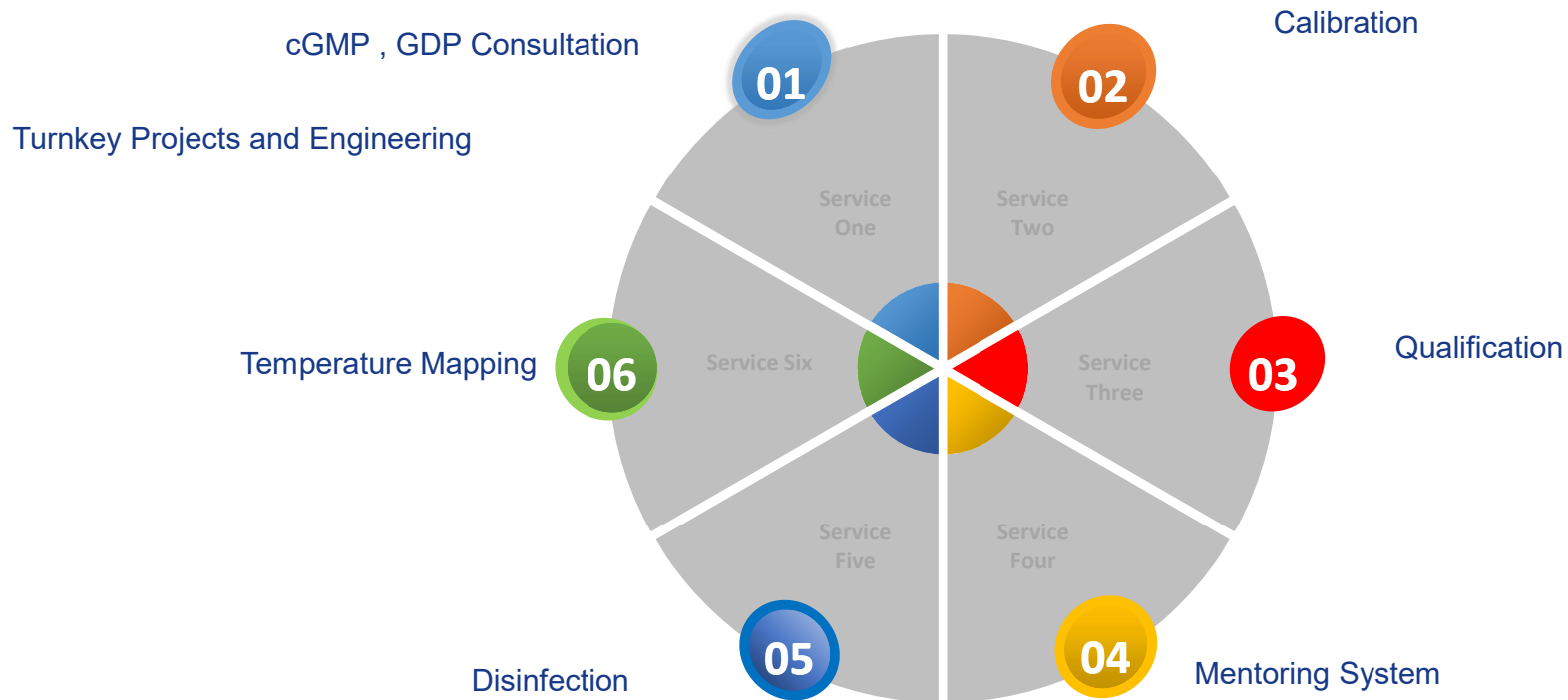


In our company, we strive to be the leading company in developing the health and food sector business in the Kingdom of Saudi Arabia, keeping pace with the latest developments and technical requirements of the sector, using the latest digital methods and digital transformation, which has become one of the most important factors for the success of organizations.

TO be our partner, Quality Compliance vision is based on “Specialty and proficiency in its field so that companies, factories and institutions that establish their business with the main target to provide certain service with a high quality that meets market requirements are able to focus on their main objective, We believe in developing and sustaining long-standing profitable relationships with our customers by providing timely, proficient, and cost-effective services within and outside the Kingdom of Saudi Arabia.



- Integrity and ethical values.
- Direct, open and honest communication.
- Commitment to customers.
- Service quality and reliability.
- Creativity and Innovation to develop effective services.
- Highest level of confidentiality to Customer property and data.





- [illegible]

cGMP , GDP Consultation Services

➤ Providing consulting services (GMP), including the following :

- ✓ Conceptual designs
- ✓ Personnel and material flow
- ✓ Room Data Sheets
- ✓ Area Classification
- ✓ General GMP Assessment for Layouts
- ✓ Primary Documents required for GMP
- ✓ Training for GMP Assessment
- ✓ Auditing GMP Facilities
- ✓ Provider Audits



➤ Providing consulting services (GDP), including the following :

- ✓ DP compliance Gap assessment .
- ✓ Complete operation and quality system establishment .
- ✓ Storage facilities design review and amendments to comply with GSDP standards.
- ✓ Qualification / mapping of cold rooms & fridges, warehouses and transportation vehicles, Validation .

Turnkey Projects and Engineering

- Technical Consulting
- Conceptual, detailed and final design
- URS preparation and review
- Commissioning and Qualification
- Project Management
- Project Execution



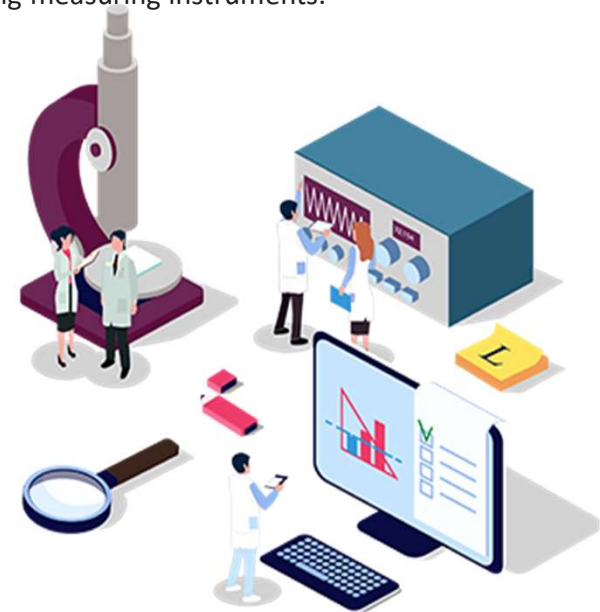
Calibration

- ❑ The Quality Compliance Company provides calibration services for measuring instruments and devices To ensure the accuracy of its results, which is one of the main requirements for obtaining To comply with GMP systems and ISO requirements for equipment Analysis, manufacturing equipment, packaging equipment and support services Buildings containing measuring instruments.

CALIBRATION/VERIFICATION SERVICES

- **Perform calibration/verification for the following:**

- Temperature (Gauge, Thermometer, Sensor, Controller, Transmitter, Transducer and Data logger)
- Pressure (Gauge, Sensor, Controller, Transmitter, and Transducer)
- Humidity (Gauge, Sensor, Controller, Transmitter, Transducer, and Data logger)
- Balances
- Ph. & conductivity meter
- Speed of the machines & motors
- Noise meter
- UV Lamp
- Timers & counters
- QC & IPC analytical instruments
- Differential Pressure (Gauge, Sensor, Controller, Transmitter, Transducer, etc...)
- Mass (Class F to M)



Qualification

- ❑ The Quality Conformity Company conducts IQ, OQ, and PQ qualification studies for buildings Devices, machines and support units for air units - water units Treatment - waste water units - compressed air and generating units Steam to ensure that it matches the purposes for which it was purchased and matches This is done according to global and local requirements and the requirements of the manufacturer By a staff at the highest levels of training and qualification and using equipment Calibrated, reference and advanced equipment with the latest international technology assigned to this field.

UTILITIES EQUIPMENT/INSTRUMENT QUALIFICATION

- **With certified and traceable instruments for the following:**
 - 💡 Water treatment systems
 - 💡 Compressed air systems
 - 💡 Lab Instrument's
 - ↓ Water Bath
 - ↓ Dissolution tester
 - ↓ Hardness Tester
 - ↓ Disintegration tester
 - ↓ Friability Tester
 - ↓ HPLC
 - ↓ GC
 - ↓ GC/MS and
 - ↓ UV Spectrophotometer



Qualification

Facility Qualification

- Design Qualification
 - To check the compliance of conceptual designs, electromechanical designs, and as-built designs to cGMP requirements.
- Installation Qualification
 - To check the proper building, structuring, and finishing of facility according to cGMP requirements.
- Operational Qualification
 - To check the proper operation of areas as it is intended to requirements.
- Performance Qualification
 - To ensure the best performance that maintain cGMP compliance and quality aspects



Qualification



QUALIFICATIONS SERVICES

- **Perform Qualification for the following:**

- Dry heat oven
- Autoclave including heat distribution and heat penetration studies
- Air Handling unit and fan coil units
- Fan coil units
- Chiller
- Cooling tower
- Heat Exchanger
- Exhaust Fan
- Boiler
- Compressor
- Water Treatment Unit
- Furnace including heat distribution study
- Dry Oven including heat distribution study
- Vacuum Oven including heat distribution study
- Incubator including heat distribution study
- Water Bath
- Stability Chamber/Room including heat distribution study
- Dissolution Tester
- Disintegration Tester
- Freezer /Refrigerator including cool distribution study
- Centrifuge
- Hardness Tester using customer kit
- Torque Meter using customer kit
- Tap Density Tester
- Friability Tester
- HPLC, GC, GC/MS
- Filling Lines: Tablet Compression, Capsule filling, Tube filling, Bottle liquid Filling, Powder Filling ...etc
- Preparation lines: Granulation, Grinding, Milling, Sieving, liquid preparation, cream preparation ...etc
- Packaging Line machines: cartoning, Printing, coding, embossing, ...etc

Qualification

QUALIFICATIONS TESTS

- Perform Qualification Tests for the following:

- Light Intensity measurements
- Noise intensity measurements
- Differential Pressure between adjacent areas
- Temperature measurements
- Humidity measurements
- Particle count measuring as per 209E and other standards
- Air velocity measurements
- Air Volume measurements for grills and networks
- Number of Air changes (ACH) measurements
- Air balancing for HVAC networks
- Vibration test measurement



- DOP (Filter integrity testing)
- Heat distribution study (empty/loaded)
- Heat penetration study (different load sizes)
- Pump Flow rate measurements
- Motor Speed (RPM) measurements
- Liquid flow meter rate
- Flue gases test (Q2 ,CO ,NO ,NO2 ,SO2 ,HC ,CO2)
- Temperature and humidity mapping (Store ,Stability chamber ,.... etc)
- Air pattern (Smoke test)

Mentoring System

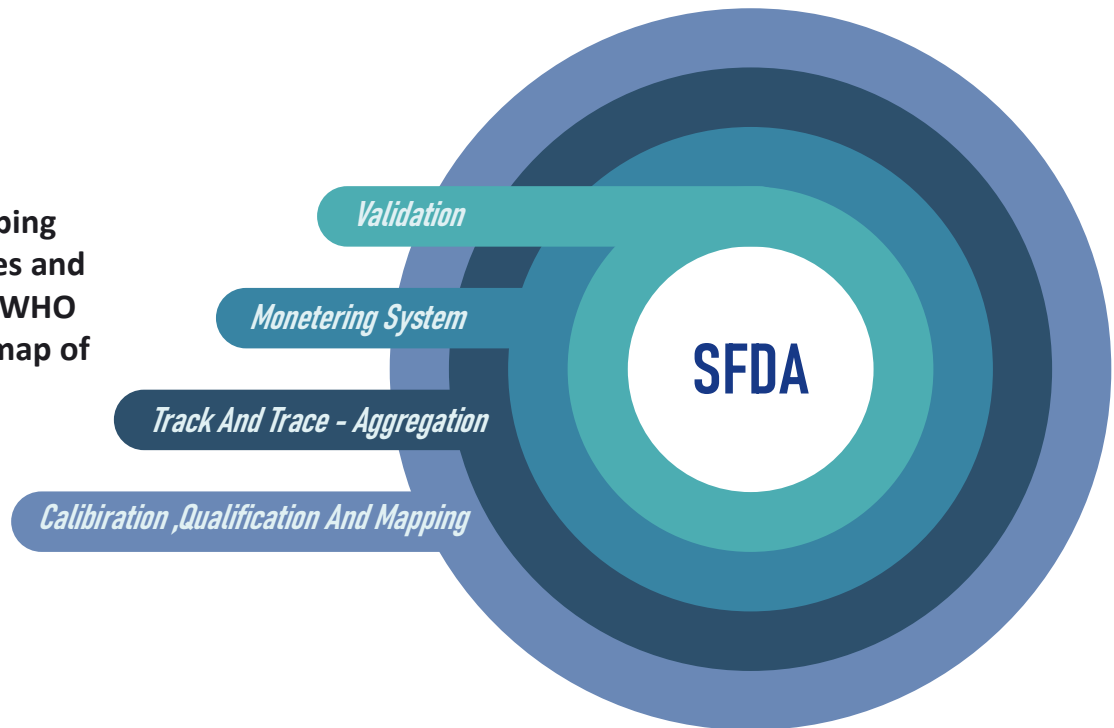
- ❑ The quality matching system is designed to contain an analytical dashboard that provides you with all the precious insights, through which you can get quick information such as the status of the connection with the monitoring system, as well as the status of the sensors that are working and not working.
- ❑ Quality Compliance Temperature Mentoring platform that can meet all business requirements in areas that require specific temperatures: warehouse stock security, cold supply chain management, temperature setting according to storage requirements, receiving alerts in real time, etc.
- ❑ You can integrate Quality Compliance Temperature Mentoring Software with CRM, GPS, accounting, payroll, human resources and other kinds of systems.
- ❑ With over 20 device integrations, Quality Compliance Temperature Mentoring Software is designed to be compatible with several hardware types.



SFDA Services

Temperature and Relative Humidity Mapping Study, We provide GSP and GDP guidelines and map-based principles that meet FDA and WHO guidelines. We can provide an outboard map of the following:

- Warehouses
- Cold Rooms
- Transportation vehicles.



Clean room & HVAC Validation

- Done as per ISO 14644, SFDA, EU & US FDA
- State of the art equipment used
- Performed by highly qualified personnel
- Can assist/support to validate the following
 - Clean rooms
 - Production area
 - Isolators
 - Laminar air flow hoods and biosafety cabinets



Qualifications Services

Can facilitate to perform the following:

- 💡 **HEPA filter integrity test**
- 💡 **Air particle counting**
- 💡 **Calculation of Air change**
- 💡 **Air velocity**
- 💡 **Sound level**
- 💡 **Light intensity**
- 💡 **Recovery time**
- 💡 **Temperature and humidity**
- 💡 **Air differential pressure**
- 💡 **Airflow Visualization**



STERILIZATION VALIDATION

Can provide validation/qualification as per 21 CFR 11 complaint system for:

- Autoclaves
- Tunnels
- Ovens
- Lyophilizes and
- SIP systems

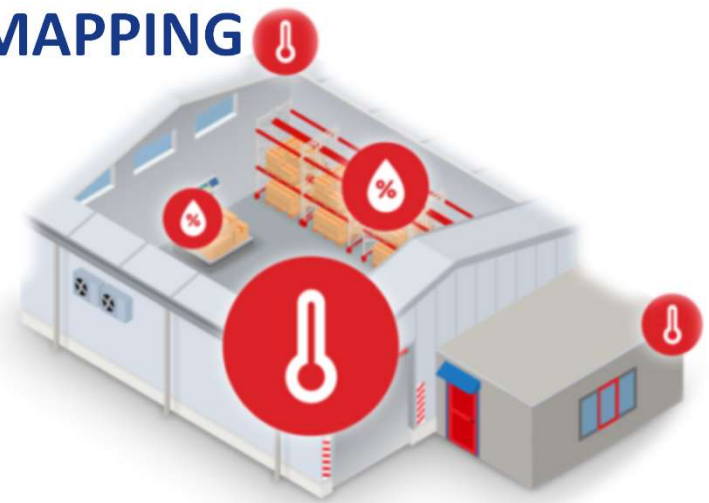
Study includes preparation of protocol, as per the current expectations, and can be modified as per the client internal requirement



TEMPERATURE/RELATIVE HUMIDITY MAPPING

- Based on current GDP, GMP guidelines
- Compliant to SFDA, EU and WHO requirements
- 21 CFR part 11 compliant software used
- Can provide mapping services for the following:

- Warehouses
- Cold Room
- Transportation vehicle
- Fridge's / Freezer's/Deep Freezer's
- Incubators
- Stability chambers
- Ovens
- Cold chain systems



COMPUTERIZED SYSTEM VALIDATION

Can provide validation services for computerized systems as per:

- 💡 cGMP requirement
- 💡 GAMP5 requirement and
- 💡 21CFR11 requirement

Study includes preparation of protocol, as per the current expectations, and can be modified as per the client internal requirement

- 💡 SAP
- 💡 ERB
- 💡 EMS/PMS
- 💡 PLC etc.



CALIBRATION/VERIFICATION SERVICES

- Provided for industrial and medical disciplines to define the accuracy of their results to comply with cGMP and ISO requirements.
- Provided at customer site
- Controlling activities by a computerized calibration manager for scheduling and reporting.
- Compliant with:
 - FDA requirement - part 11
 - EU-GMP requirement in EUDRALEX 4 – Annexa 11



Training

- Training courses are designed especially for you as per your needs.
- Assessing your current situation and interviewing concerned staff to find weaknesses, upon that we will generate appropriate training materials that obtained from real life.
- Our training will satisfy regulatory requirements as well as business needs.
- Evaluation of trainees is done to insure the maximum benefit.
- Training topics may include but not limit to:
 - 💡 Understanding of process validation
 - 💡 Management of annual product review
 - 💡 Internal/external/regulatory audit management
 - 💡 Cleaning/ cleaning validation
 - 💡 Quality System (Documentation, Change Control, Deviation and CAPA managements)
 - 💡 General GMP
 - 💡 GMP for Engineers
 - 💡 Aseptic processing
 - 💡 Quality risk management



Regulatory Affairs Services

Drug Development:

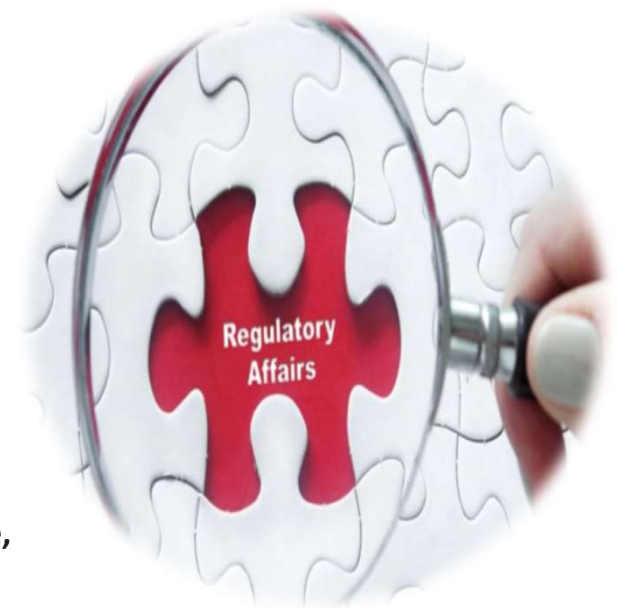
- Product Formula
- Process designing
- Selection of API and Excipients suppliers (From SFDA or FDA suppliers)
- Stability data
- Test method validation
- Technology transfer and support in validation batches
- Preparation of Module 3 in CTD File

Product Registration

Our long experience in this field enabling us to provide you a unique service, this service run by Ex-SFDA staff so your file will be identically evaluated

Before submission We insure the following:

- Shorter time for registration
- Easy to zero inquiries
- Preparing the needed documents before application



Certified By



ISO 9001

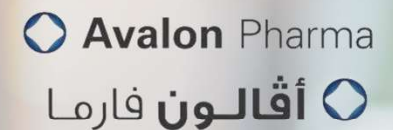


SFDA



ISO 17025

OUR CLIENTS



OUR PARTNERS



Elitech[®]

tempmate.[®]



Our Own Products





Thanks