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Quality Advisory Consultancy

Corporate Presentation

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Introduction

PharmaMantra™ is a **Q**uality, **A**dvisory, **C**onsulting firm founded by Udaykumar Rakibe, M.Pharm. Ph.D., MBA in August 2017. Udaykumar is highly motivated result oriented professional with three decades plus domain experience in the *Pharmaceutical Quality* & Operations Management in Regulatory GXP/CGMP arena. Steering organization through ***complex Quality & Regulatory challenges***, ***remediation***, transitions & building an empowered Quality Operations Team which is capable and empowered to deliver results within highly competitive products and regulatory environment.

Demonstrated track record, by leading cross functional global teams to achieve desired tactical, strategic business objectives with continued assurance of product quality and GMP compliance.

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Introduction

Enabling the process to facilitate the management at Board and Shop-Floor level to identify and help delivering strategic and transformational Quality leadership drive for imparting, Culture of Pharmaceutical Quality. Worked at global organisations across continents/ geographies to provide successful international growth initiative in Pharmaceutical, Bio-Pharmaceuticals, Herbal, Device, Healthcare, Cosmetics industry.

Mentoring, Training & handholding the site and corporate management to support and bring in the desired SOC – State of Control.

Leadership Role - Quality Professional

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Quality

- Strategy and advise - to formulate and implement a sustainable Quality System
- Gap Assessment Audits – GxP, Pre-approval inspection (PAI) readiness
- WL/ 483, Regulatory inspectional Review, Response writing (post inspection)
- Road Map, as corrective action plan (CAP), OAI/ VAI remediation & communication
- US Products Release, Review the Data, QMS assessment, Analytical & Batch Records
- Training & Certification - GxP compliance, Data Integrity, Investigation CAPA, Root Cause,
- Due diligence of product, facilities
- PDE & OEL Certification, as per EMEA Guidance

Advisory

- Greenfield/ Brownfield- New Project, ideation and advice for Facility, Product, Contract Test Lab
- R & D, Scale-up, Manufacturing, Quality & Compliance Strategy
- Support review the prevailing- QMS. Review, Execution, Implementation
- Instill the Culture of Quality

Consultancy

- Quality Management – R & D, Manufacturing Operations (API, DF, Devices), CRO, CMO
- Regulatory batches, data review, help in dossier submission and site readiness
- Resource Management for SOC (state of control)
- Remediation Program, GxP Compliance Strategies

- **Dabur Pharma Ltd** – Onco and Gen Injectable; Project & QMS
- **Gland Pharma** – QMS General Injectable; MNCs Clientele
- **Ranbaxy Labs Ltd.** – Corporate07-Quality OPS 07; Remediation FDA/ MHRA
- **Intas Pharma** – Project SEZ; QMS Remediation
- **Wockhardt Ltd.** – Remediation FDA/ MHRA; Re-organisation Quality
- **Morison Ltd.** – Commercial SriLanka Mkt; Prepare EU Mkt; Re-organisation Quality

Bio-Profile Udaykumar Rakibe, Ph.D. MBA

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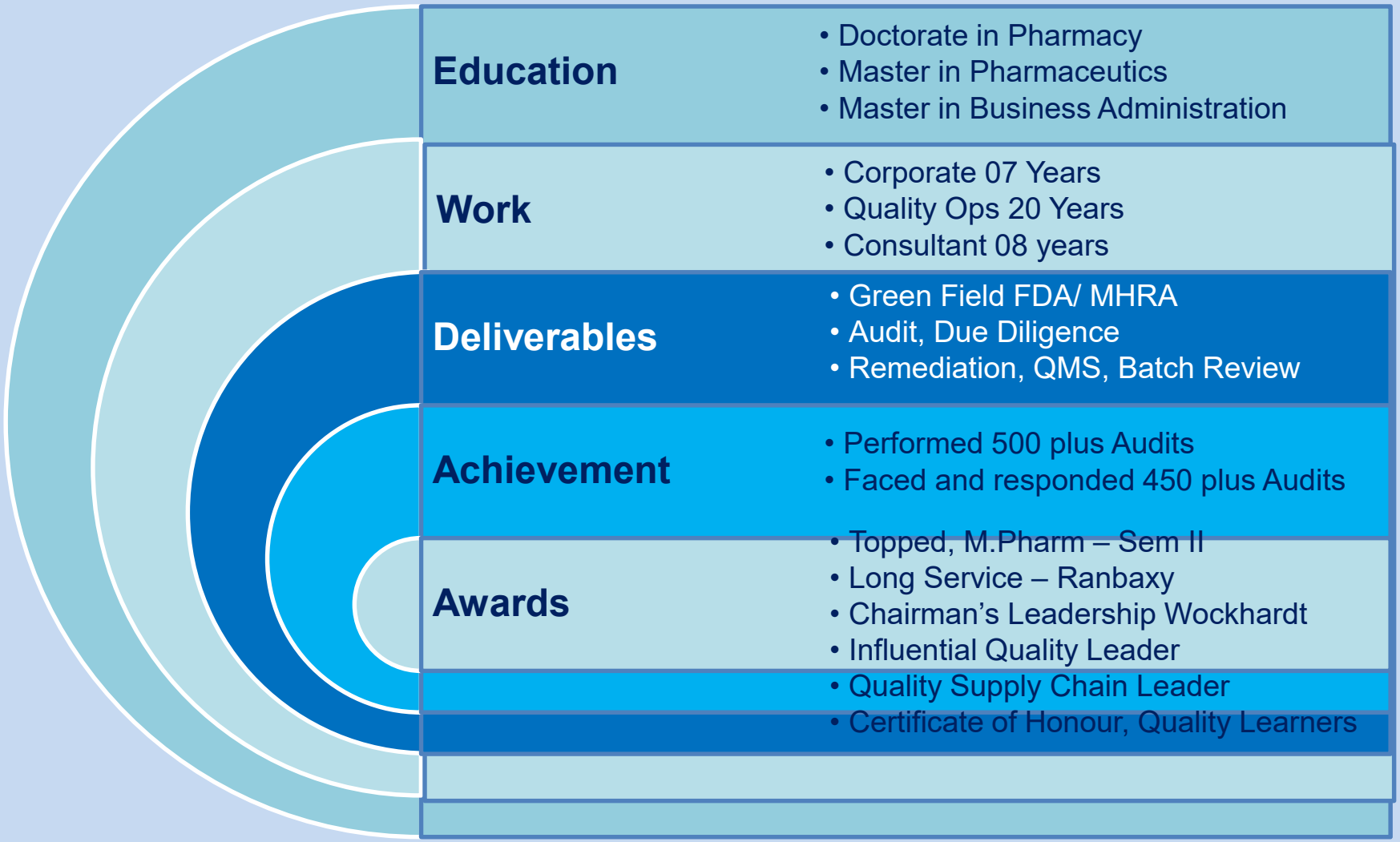

Critical role by Udaykumar Rakibe, Ph.D. MBA
As a Quality Leader

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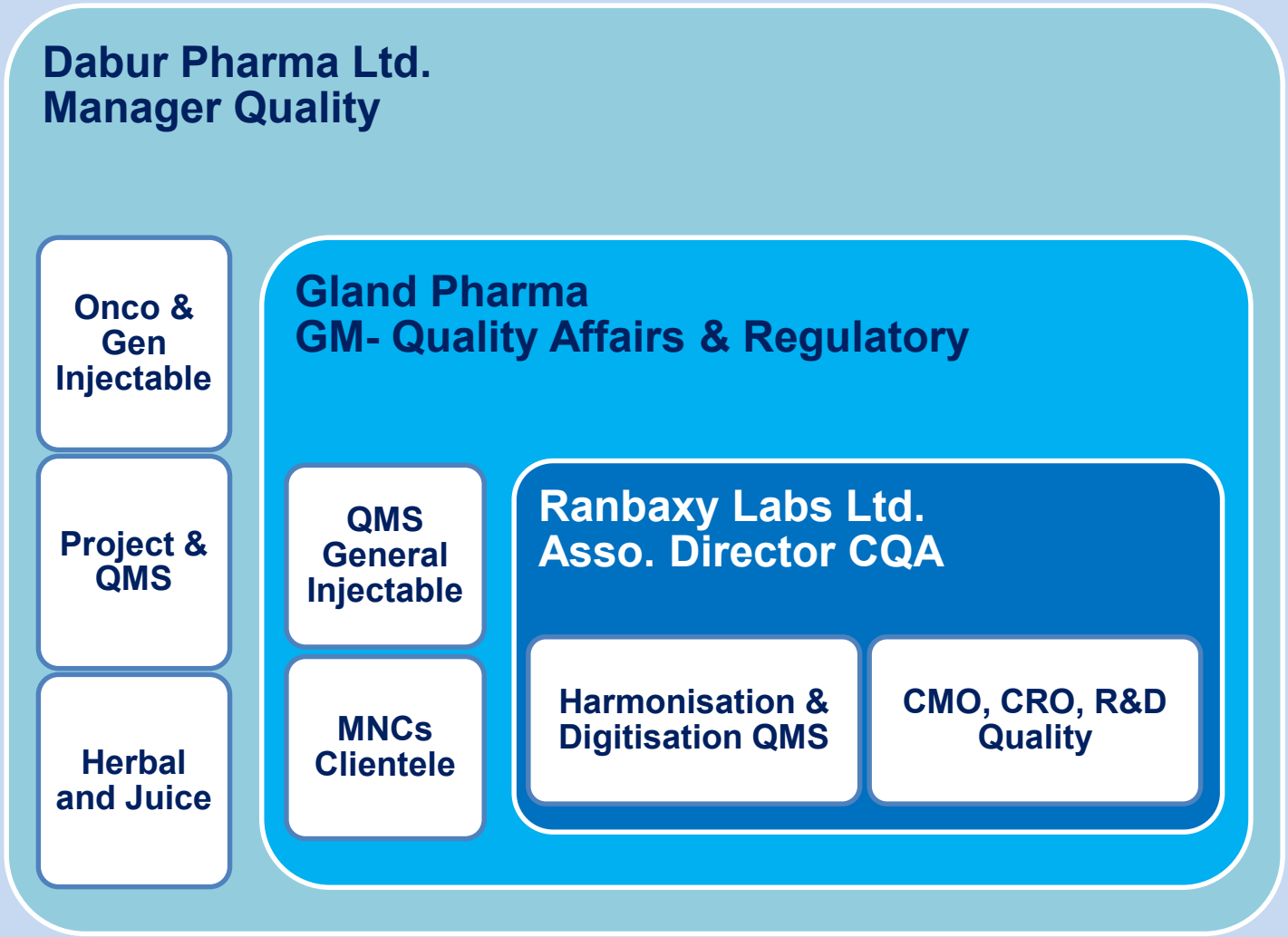

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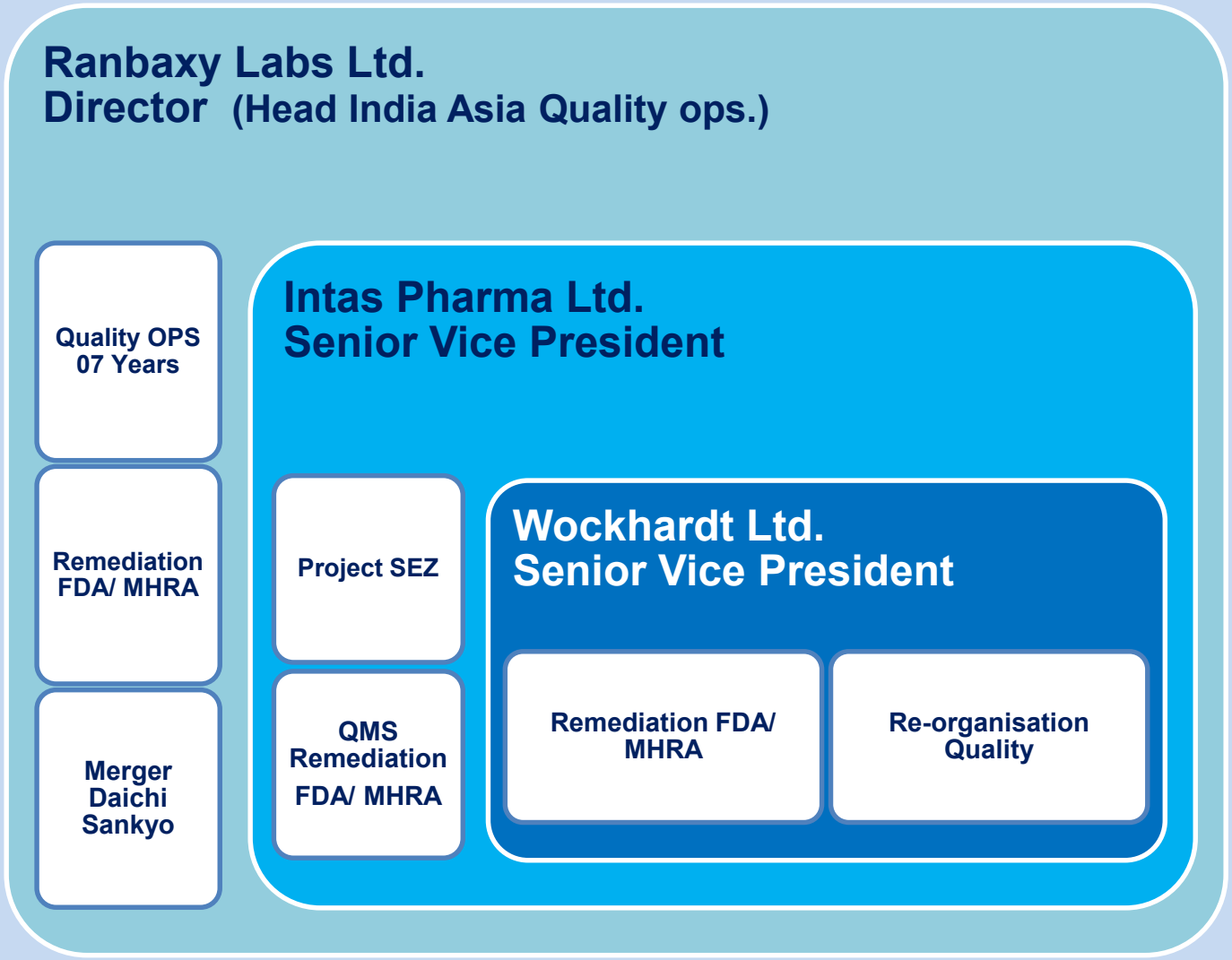

Critical role by Udaykumar Rakibe, Ph.D. MBA
As a Quality Leader & Advisor

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Pharco Group Alexandria, Egypt,
Mentor to MD & Director Quality

- Quality CGMP
- Gap QS & Facilities
- API(01site) DF(05site)

Morison Ltd., Colombo, Sri Lanka,
Chief Quality Officer

- EU CGMP
- Quality Re-organisation
- Gap QS & Facilities
- Commercialisation Sri Lanka

Span of Control, Udaykumar Rakibe,Ph.D. MBA
As a Quality Leader

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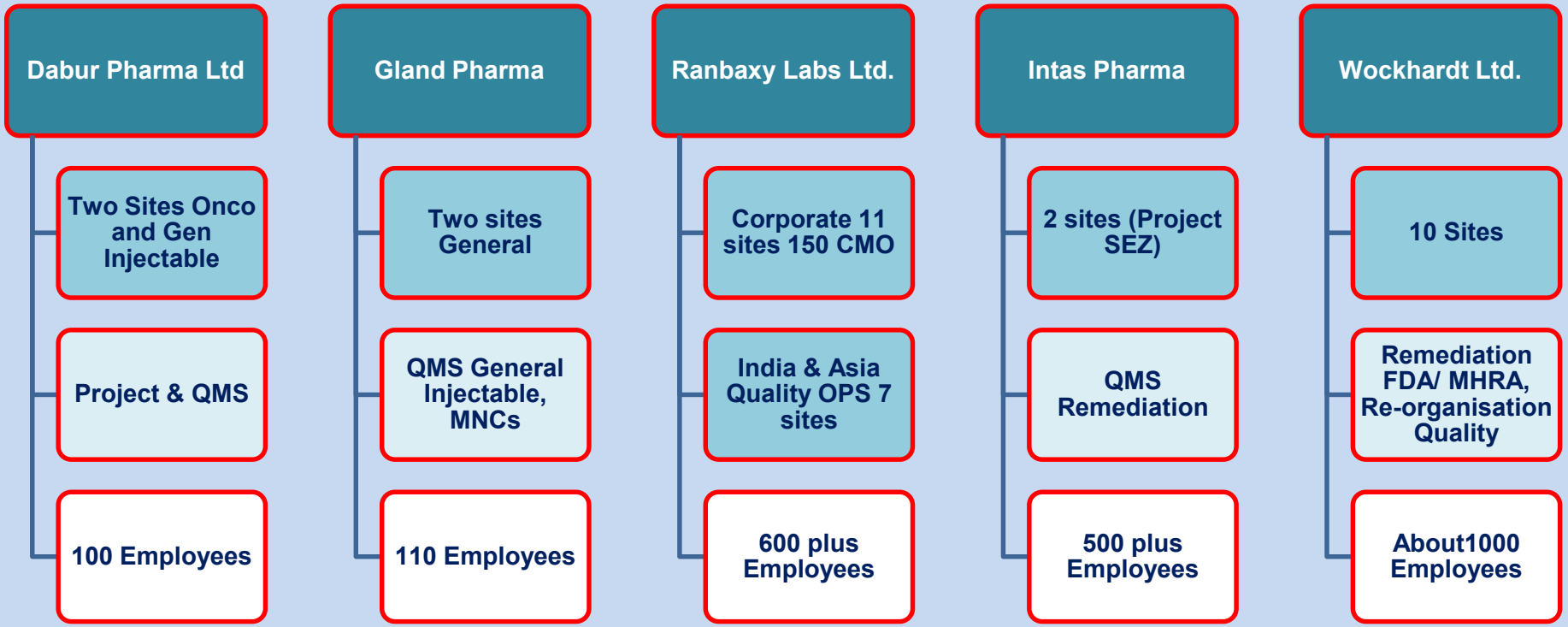

Audits faced by Udaykumar Rakibe Ph.D. MBA
As a Quality professional

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Organisation	Agency	Category	Activities	Designation
Dabur Pharma	MCC, OGYI, WHO	Onco Injectables	Audit & Response	Head Quality
Gland Pharma	US-FDA, ISO 9001, MNC Clientele	Gen. Injectables	Audits, Response	Head Quality
Ranbaxy Lab	FDA/ MHRA India/ Asia/ MENA/ Africa	API Gen/ DF (all categories)	483/ WL/IA/AIP	Corp. Quality
Ranbaxy Lab	FDA/ MHRA India/ Asia Region, 8 sites	API Penem/ Gen/ DF (all categories)	483/WL/IA	Head Quality
Intas Pharma	FDA/ MHRA Matoda, SEZ	API & DF Onco/ Gen	483	Head Quality
Wockhardt Ltd.	FDA/ MHRA India/ UK/ US, 10 sites	API Gen/ Cepha/ DF/ Devices	483/WL/IA	Head Quality

Note-

- *More than two decades lead, **participated & responded - 450+ Regulatory** Audits, as Head of Regional/ Site Quality.*
- *Spearheaded the formulation of **Corrective Action Plan,** CAP for Remediation and Single Point Of Contact, **SPOC** for 3rd party and regulatory Audits and responses.*
- *Additionally performed **400plus** (between 2000-2007), **due diligence & cGMP** Audits in Global Corporate Quality role.*

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Services We Provide

Quality

Advisory

Consulting

Engineering & Projects

Training

Services We Provide

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Esteemed Clientele
GMP Activities for –

1. Abbott, 2. Aragen, 3. Anavex Inc. USA, 4. Aristo Pharma Pvt. Ltd., 5. Baxter, 6. Bliss GVS, 7.Baroque Pharma, 8. Brassica Pharma Ltd., 9. Blue Ocean Compliance, 10. Ciron Drugs, 11.ChromeCore, 12. Dicel ChiralTech-DCTI, 13. Emcure Lab. Ltd., 14. Eisai India, 15.Hetero Labs, 16. IQGENX, 17. InnovaTech, 18. Kilitch Healthcare India Ltd., 19. Kopran, API(Mahad) & 20. Kopran,DF(Khopoli), 21. Morison, Sri Lanka, 22. MJ Biopharma, 23. Megafine Chemicals Dindori, 24. Megafine Chemicals Vapi, 25. Optimus Pharma., 26. Pharco Group-Alexandria, Egypt (6 sites of API & DF), 27. Sri Krishna Pharma, 28. Steril-Gene, 29. Syngene, 30. Qualigens, 31. QU-LLC, 32. TagBox, 33. McKinsey, 34. EaishMan, 35. WHO Geneva

Mentor, Board of Advisors-

1.Govt of Maharashtra, Education Ministry- Technical Committee member for review of Pharmacy Course Curriculum and Education Policy & Recommendations (2025-2031), 2. UBM Conference, 3. BlueTech Conference, 4. EBM Conference, 5. CPhI Conference, 6. Pharma World CaseCon, 7. PharmaNow

Services We Provide

Role we play -

Enabling the process to facilitate the management at Board and Shop-Floor level to identify and help delivering strategic and transformational Quality leadership drive for imparting, *Culture of Pharmaceutical Quality*. Worked at global organisations across continents/ geographies to provide successful international growth initiative in Pharmaceutical, Bio-Pharmaceuticals, Herbal, Device, Healthcare, Cosmetics industry.

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Services We Provide

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Deliverables and achievements –

We have experience in on-site and off-site assessment of the GXP data. Provide effective compliance strategy and QIP (Quality Improvement Plan) for Quality Management. Services provided to various clientele- API- Intermediates, API/ DS, DF, Devices, IT- software, AI-ML.

Since, March 2020; we adopted seamlessly to go virtual & did CGMP activities due to the exigency caused due to Covid-19 Pandemic. During subsequent Lockdown we provided the remote review & CGMP assessment for developed Markets like USFDA, EU region – QMS Review, Batch Record Review and Release of the Sterile Finish Products. Proposed the WL Remediation strategy, Plan and CAP. Virtual CGMP Audit and due diligence. Virtual Training and mentoring and advisory for Global corporations.

Services We Provide

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Quality Learners, group formed during Covid-19 Pandemic, in Oct'2020, having strong 440+ members, who are - Mentors, Educators/ Teachers, Ex-colleagues, Referrals; having extensive rich experience in Pharmaceuticals, Biotechnology, Device, Pharma 4.0, Six Sigma.

Members have worked in Academics, and in Industry as Head of R&D, Technology Transfer, Regulatory Agencies, Quality & Regulatory, Manufacturing, Engineering.

Facilitation for a weekly talk, hosted by myself supported by a core committee.

Objective of QL forum is a weekly discussions, expert talk, deliberation on current topic. A Corporate Social Responsibility (CSR) initiative of PharmaMantra™, & associates; where the knowledge is shared as mutual experiential leaning experience. It is giving back to the society by interaction, knowledge sharing through Weekly Webinar on tech topics from API, DF, Device, Biosimilar, Pharmaceutical.

A very interactive & motivating learning cum networking/ digital platform enabling various leaders/ SME - R&D, Quality, Production, Regulatory, FDA, WHO. Till date we have hosted/ conducted 236 webinars/ talk-session.

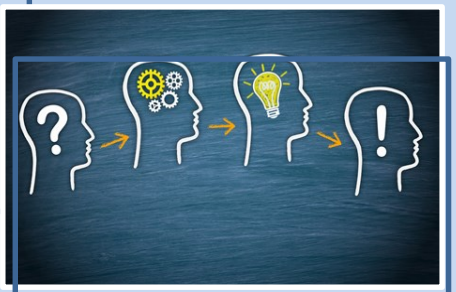
Services We Provide

Greenfield Project, Facility & Equipment Gap assessment

Resource assessment and Remediation support

CGMP Gap Assessment

PDE Certification



Strategy & Consulting

Training

Services We Provide

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Quality

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Services We Provide

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Advisory

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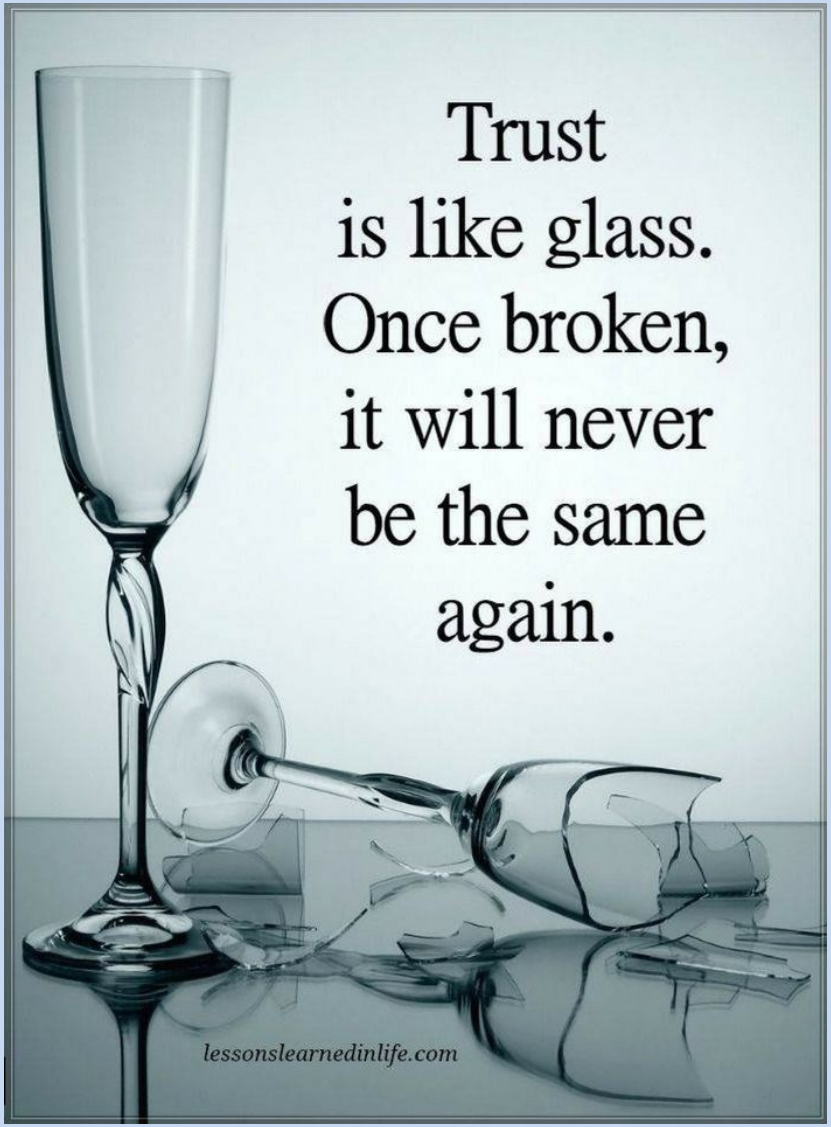
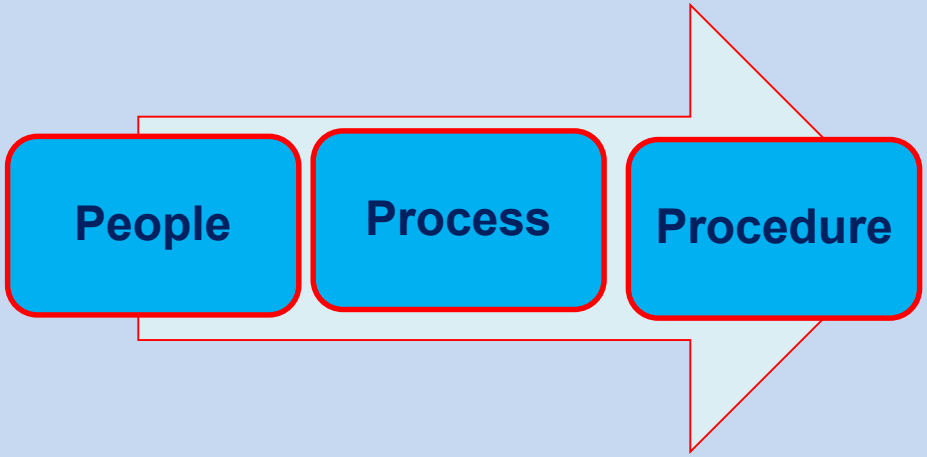

Trust
is like glass.
Once broken,
it will never
be the same
again.
lessonslearnedinlife.com

Purpose

To support organizations achieve their potential and proactively reach the desired milestones with a planned - ***Strategy, Plan and Execution***.

This may be achieved by focusing on the *3Ps* –

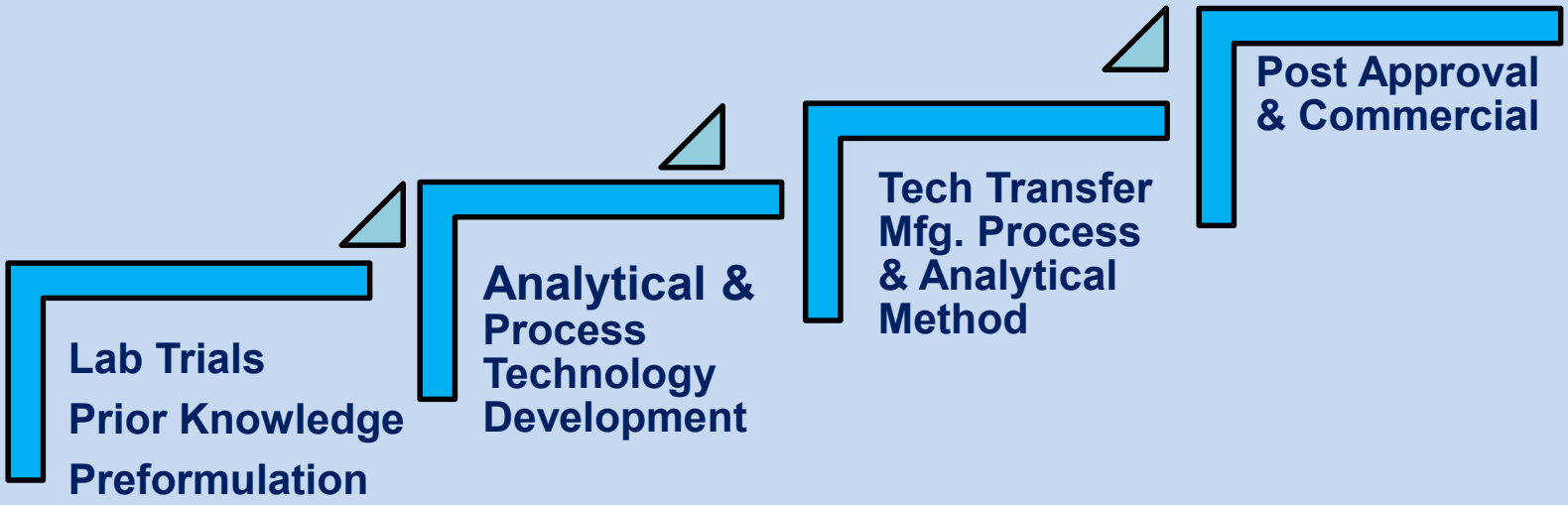


This can be documented as commitment in ***Quality Policy*** signed by the Chairman or Managing Director. Giving clarity as Organisational - ***VISION*** and implemented as short term and long term Strategy as ***MISSION***.

Scope

To support organizations achieve their ***Vision, Mission and Strategic Milestones*** in end to end operations management. Integrating the New product development and operations to synchronize the ***Timely Launch*** and meet the ***Business Goals*** **"Right First Time and Every Time".**

Industry Relevance



This may be achieved by focusing on the above functions in the organisation – ***adequate project management and timely escalation of issue*** to Management can lead to harness the potential and proactively reach the desired milestones with a planned - Strategy, Plan and Execution.

Industry Perspective

New Product development

- Prior Knowledge
- Regulatory expectation
- Guidance
- Process Technology
- Method of Analysis
- Q8(2)QbD
- Design Space
- PAT
- eDocumentation
- Data Integrity

Technology Trans & Manufacturing scale-up

- Scale-up
- Clinical/ exhibit batches
- Change in the mfg/ analytical method
- Change control
- Q9 Risk Assessment
- Q10 Quality System, Review
- Q12 Lifecycle mangement
- eDocumentation
- Data Integrity

Post Approval - Commercialization

- Process for investigation and analysis of any failure,
- Incident or discrepancy in order to identify the root cause/probable cause.
- To provide a brief description of investigation methods and documentation to assist the investigation team.

Regulatory Strategy & Risk Assessment

Lab to Launch expectations…

Complex Drug Development Process

The drug development process is complex, consisting of many interrelated business activities and functional constituents participating in the *"Lab to Launch"* of any given product (Figure 1).

Figure 1 *"Lab to Launch"* Continuum

Regulatory Strategy & Risk Assessment

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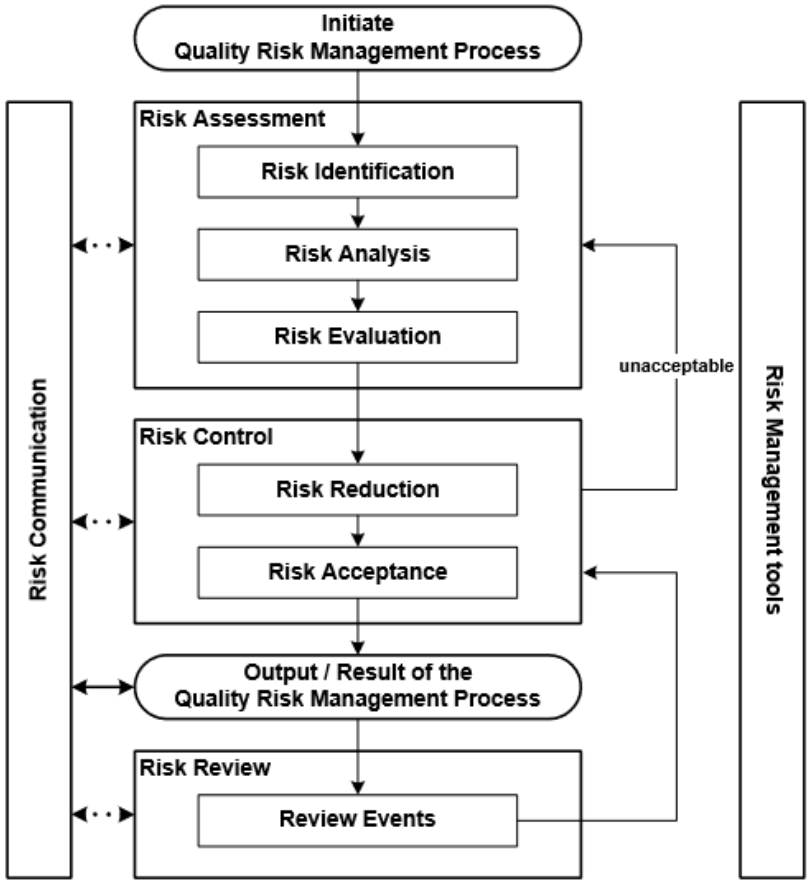
Figure 1: Overview of a typical quality risk management process



5 step Mantra for Willing Transformation

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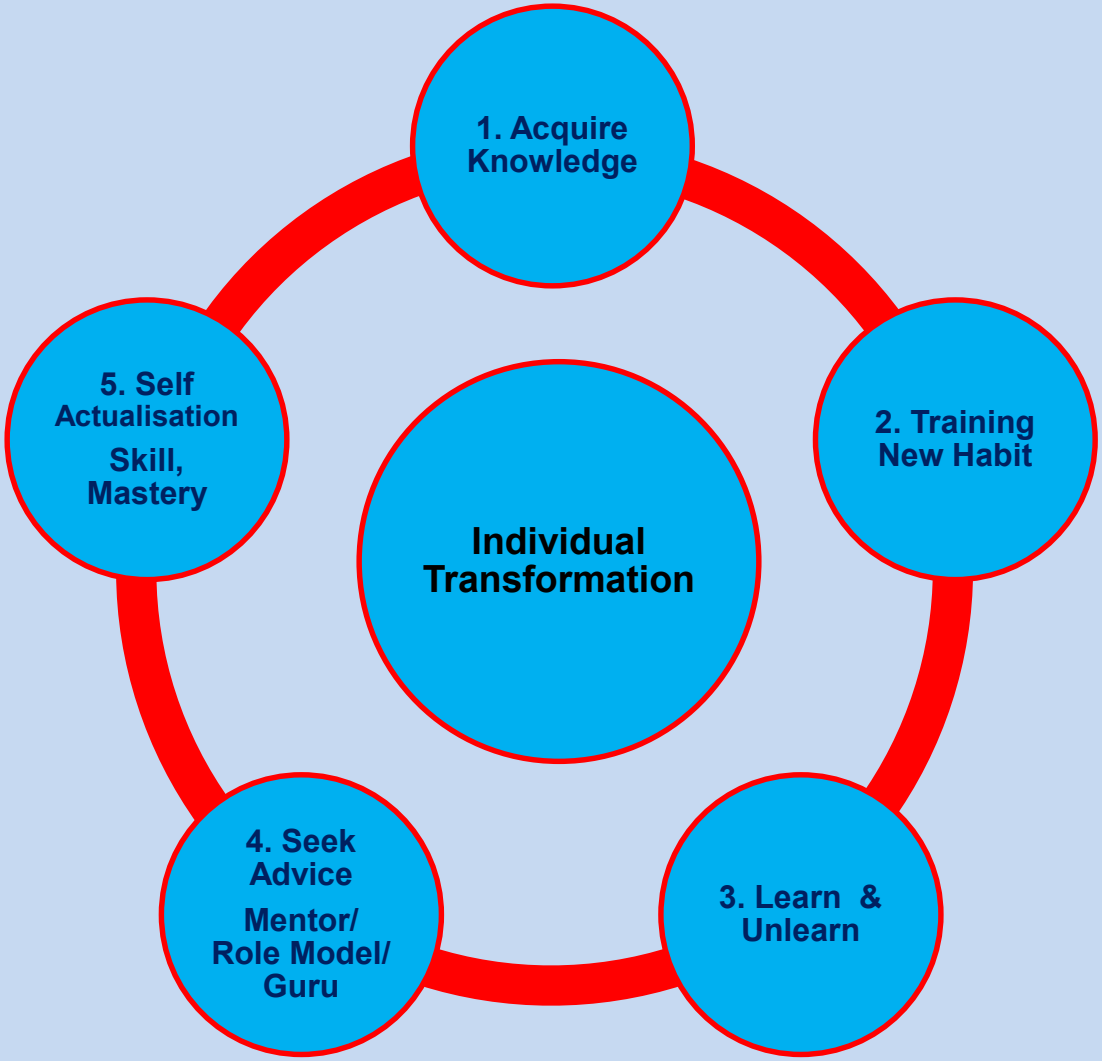

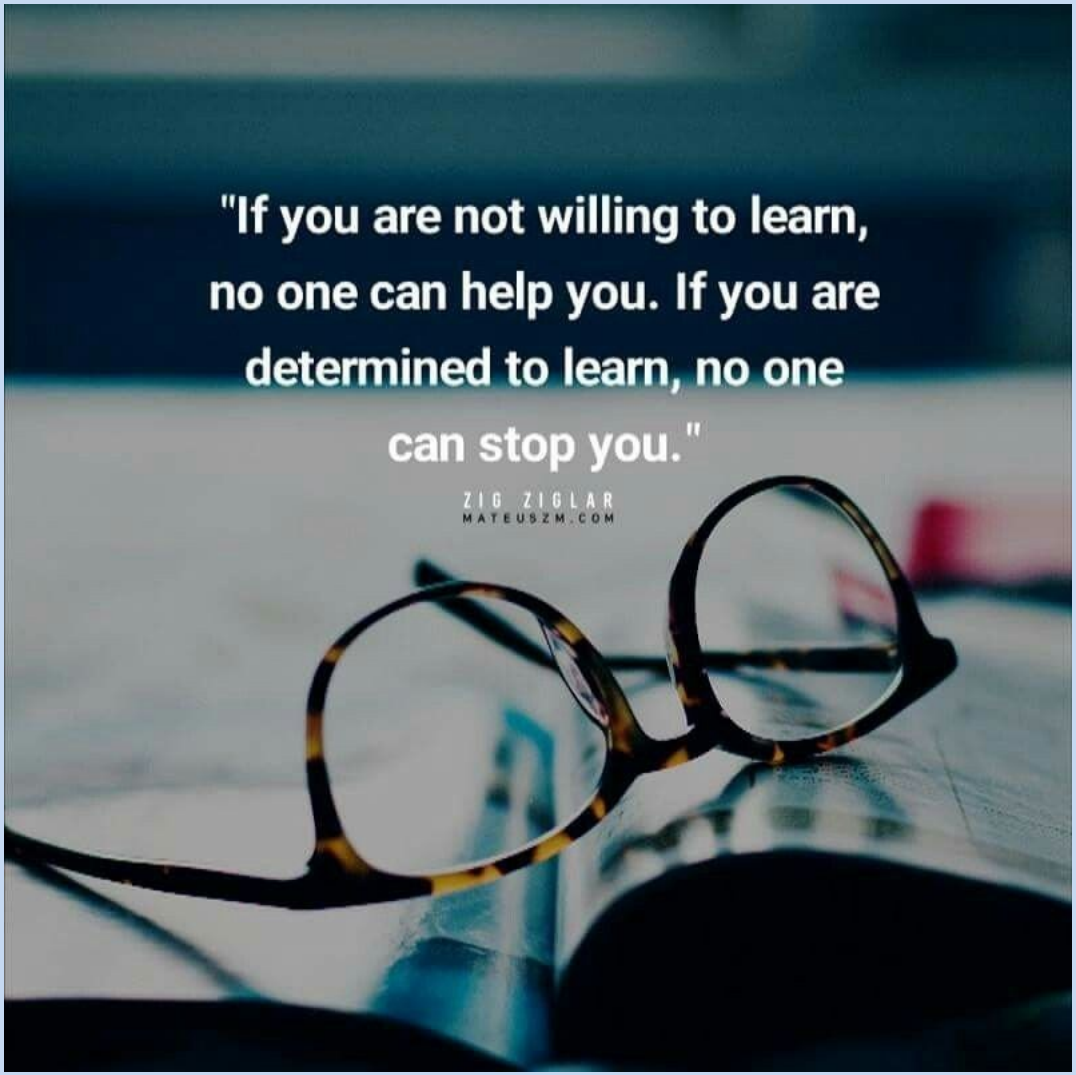
"If you are not willing to learn,
no one can help you. If you are
determined to learn, no one
can stop you."
ZIG ZIGLAR
MATEUSZM.COM

Lessons Learnt –
Scaling manufacturing to meet commercial requirements

Understanding the functional requirements of each of the “swim lanes” and the inter-relationship across these constituents will define challenging areas to focus on for initiating this activity. A template of common drug development activities and constituents supporting this activity provides a starting point for many organizations beginning a business transformation process.

Lessons Learnt – ALCOA

Although the **cGMPs** articulate a number of the expectations for data quality, the **GLP** regulations, , are the first FDA regulations which bring the ALCOA elements of data quality together in a comprehensive fashion.

For this reason**, the GLP requirements pertaining to data quality elements**, particularly **21 CFR 58.130(e)** which articulates virtually all the **elements of ALCOA**.

This acronym stands for :

1. **A**ttributable,
2. **L**egible,
3. **C**ontemporaneous,
4. **O**riginal and
5. **A**ccurate.

Lessons Learnt – ALCOA+

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The following are some general definitions, paraphrased from the Pharmaceutical Inspection Co-operation Scheme (PIC/S) (1), that can be used for understanding the elements of ALCOA and **ALCOA+:**

1. **Attributable:** The data generated or collected must be traceable back to the individual who generated the information.
2. **Legible:** The data recorded must be readable and permanent.
3. **Contemporaneous:** The results, measurements, etc. must be recorded at the time the work is performed.
4. **Original:** Original or source data are the record, report, notebook etc. where the data point was initially recorded.
5. **Accurate:** The data recorded must be complete, consistent, truthful, and representative of facts.

Plus- CCEA

1. **Complete:** Information that is critical to recreating and understanding an event. This would include any repeat or reanalysis performed on a laboratory test sample.
2. **Consistent**: The data are presented, recorded, dated, or time-stamped in the expected and defined sequence.
3. **Enduring**: The data or information must be maintained, intact, and accessible throughout their defined retention period.
4. **Available**: The data or information must be able to be accessed at any time during the defined retention period.

PharmaMantra™ –Modus Operandi

US FDA and EU/ EDQM related activities performed in two ways Independently & Collaborative approach –

1. ***Independent approach –***

*M*anaged by myself & invoiced and reported under "PharmaMantraTM".

2. ***Collaborative approach –***

Managed by other either by a consulting firm, as partner or consortium, supported by myself/ PharmaMantraTM.

PharmaMantra™ –Modus Operandi

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A pool of experts is formed, members are based in India and developed countries, viz. US, EU –

1. The SMEs in consortium are senior professionals having core experience - 20 to 50+ years. The age range is between 40 to 75 years.

2. All are having professional experience and exposure, regulated markets.
   - Pharmaceutical, Chemical Research and Manufacturing
   - Toxicological and Clinical
   - PAT, Pharma 4.0, Devices
   - CSV and GXP gap assessment and remediation
   - Sterile product manufacturing & Microbiology
   - Ex US FDA, CDER and Innovative technologies, Device, Biosimilars, Generic Drugs

3. Already established as consultants and advising in the developing economy and developed economy.

PharmaMantra™ –Modus Operandi

A pool of experts is formed based in India and developed countries, viz. US, EU –

Continued-

4. Individuals are experienced in evaluating GXP, CGMP systems of pharmaceutical manufacturers (viz. APIs, excipients, finished dosage form, analytical testing laboratory, medical device, and packaging).

5. The SMEs, managed small to large projects, conduct effective GMP, Due Diligence, Vendor Qualification audits and has good understanding of quality system, material system, facility & equipment system, production system, laboratory control system, packaging and labelling system (encompassing all the six systems of a pharmaceutical cGMP). Also expertise in evaluation of sterile manufacturing facility and various sterilization processes.

PharmaMantra™ –Modus Operandi

A pool of experts is formed based in India and developed countries, viz. US, EU –

Continued-

6. The team has experience in facing inspection by various health authorities (US FDA, EU, MHRA, EDQM, WHO, ANVISA etc.). Apart from facing number of facility inspections, the team has combined experience of facing 100 plus facility inspections from US FDA. Thus team is enriched with knowledge and experience of Regulatory agencies expectations. We have completed projects on quality management services for pre-inspection evaluation of QMS for EDQM and US FDA inspections of API and DF facilities.

7. Supported client in preparing response to 483 Observations issued at the end of US FDA Inspection of API facility. Gap assessment of QMS and remediation at API, Device & DF site. We had been associated with the client in preparing presentation and participated in face to face meeting with US FDA for GMP related Regulatory Meeting (API & Formulation facility).

PharmaMantra™ –Modus Operandi

A pool of experts is formed based in India and developed countries, viz. US, EU –

Continued-

8. Dossier outsourcing, Product and Method Development, India, ROW and US and EU markets.

9. Supported in development, validation and execution of the software and hardware for facility management. Facility CSV and equipment qualification and life cycle management, as per 21CFR, GAMP.

10. Assessment and certification of the PDE, Permitted Daily Exposure for API and Dosage Forms.

11. Training on the GXP Topics, emphasis on the learning and un-learning by willing transformation. Workshops including Presentation, Case Studies, Movies, for Audio and Video impact for enabling effective learning.

Summary –

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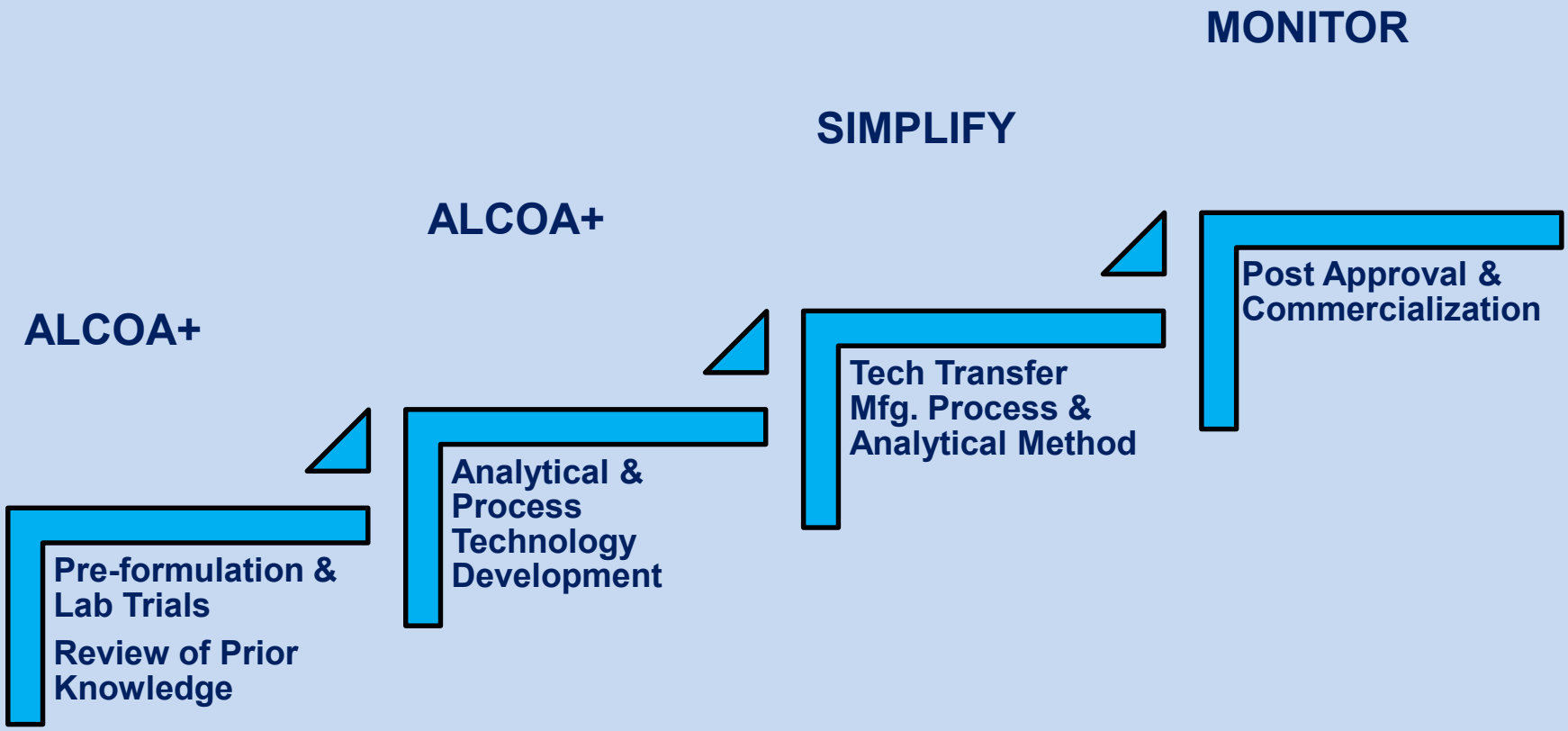
People → Process → Procedure

2 sides of a coin may be different- does not lose value, Opportunity & Challenges are always there…

Learning……Challenges – Documents…..Records…



Learning……Challenges – Unlearning…..No Repeats….mistakes

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New Product development

- Identification of Candidate – Business Case
- Develop – Dosage, Prototype Process, Method (innovator)
- Bio-batches, Clinical, BA/ BE studies
- Investigations of Failure - Learning

Technology Transfer & scale-up

- Scale-up of Batch Process, Method of Analysis, Specifications,
- Validation, Reproducibility, Process Capability
- Investigations of Failure – Process Optimisation

Post Approval & Commercialization

- Change Control - Batch Process, Method of Analysis, Specifications,
- Investigations of Failure - Trend
- CPV, Monitoring the Process Capability
- PLM (lifecycle management)

Bhagavad Gita:

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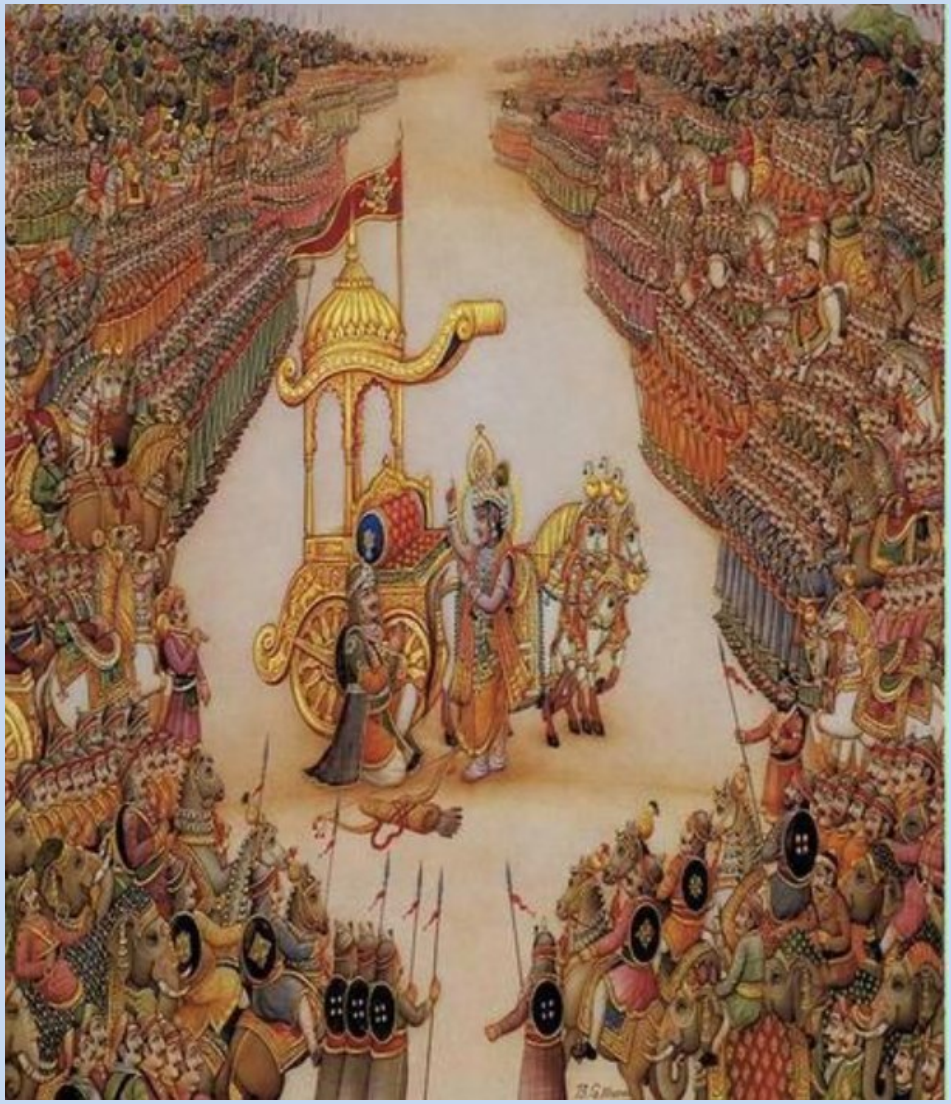

Willing Transformation

Arjuna was advised by **Krishna** in battlefield.

1. Listened
2. Thought
3. Acted

Sanjaya, who was viewing, listening and telecasting the happenings to **Dhritrashtra.**

Dhritrashtra was listening to the blow by blow account.

The three individuals were listening….only one heard and then was willing to transform. Arjuna's ***self was involved*** in the process of transformation and then he led the Pandavas…

Arjunas, transformation lead to the Pandavas victory in 18 days Mahabharata.

Bhagavad Gita: Chapter 4,Verse 34

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तद्विद्धि प्रणिपातेन परिप्रश्नेन सेवया |
उपदेक्ष्यन्ति ते ज्ञानं ज्ञानिनस्तत्त्वदर्शिनः || 34||

tad viddhi praṇipātena paripraśhnena sevayā
upadekṣhyanti te jñānaṁ jñāninas tattva-darśhinaḥ

tat—the Truth; *viddhi*—try to learn; *praṇipātena*—by approaching a spiritual master; *paripraśhnena*—by humble inquiries; *sevayā*—by rendering service; *upadekṣhyanti*—can impart; *te*—unto you; *jñānam*—knowledge; *jñāninaḥ*—the enlightened; *tattva-darśhinaḥ*—those who have realized the Truth

BG 4.34: Learn the Truth by approaching a spiritual master. Inquire from him with reverence and render service unto him. Such an enlightened Saint can impart knowledge unto you because he has seen the Truth.

On hearing that sacrifice should be performed in knowledge, the natural question that follows is, how can we obtain spiritual knowledge?

Shree Krishna gives the answer in this verse.

He says: 1) Approach a spiritual master. 2) Inquire from him submissively. 3) Render service to him.

Bhagavad Gita: Chapter 4, Verse 22

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यदृच्छालाभसन्तुष्टो द्वन्द्वातीतो विमत्सरः |
समः सिद्धावसिद्धौ च कृत्वापि न निबध्यते || 22||

yadṛichchhā-lābha-santuṣhṭo dvandvātīto vimatsaraḥ
samaḥ siddhāvasiddhau cha kṛitvāpi na nibadhyate

***yadṛichchhā*—which comes of its own accord; *lābha*—gain; *santuṣhṭaḥ*—contented; *dvandva*—duality; *atītaḥ*—surpassed; *vimatsaraḥ*—free from envy; *samaḥ*—equipoised; *siddhau*—in success; *asiddhau*—failure; *cha*—and; *kṛitvā*—performing; *api*—even; *na*—never; *nibadhyate*—is bound**

BG 4.22: Content with whatever gain comes of its own accord, and free from envy, they are beyond the dualities of life. Being equipoised in success and failure, they are not bound by their actions, even while performing all kinds of activities.

While living in this world, nobody can hope to neutralize the dualities to have only positive experiences.

Then how can we successfully deal with the dualities that come our way in life? The solution is to take these dualities in stride, by learning to rise above them in equipoise in all situations.

This happens when we develop detachment to the fruits of our actions, concerning ourselves merely with doing our duty in life without yearning for the results.

Bhagavad Gita:

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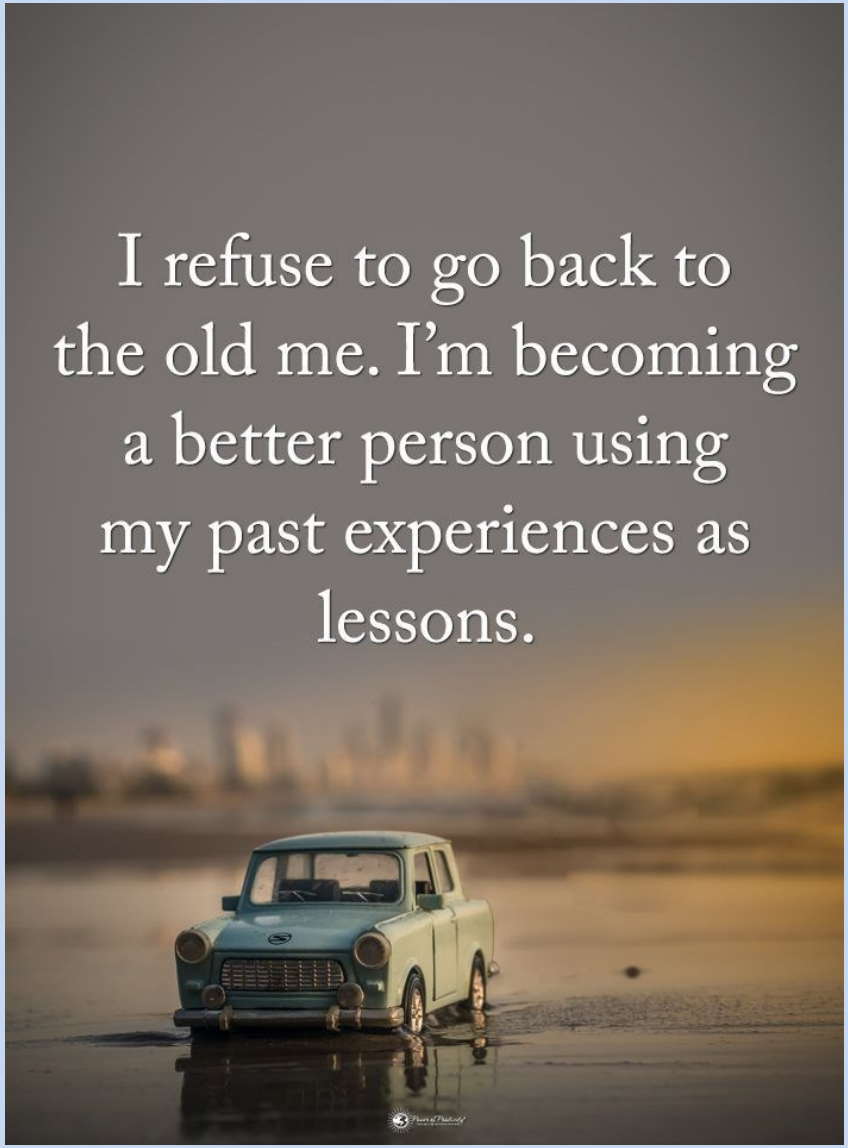
5 step Mantra for Willing Transformation

1. **Acquiring Knowledge**
2. Regular **Training** and develop a new **Habit**; eliminate bad habits
3. **Learning** & be receptive – environment, changes; **Unlearning**
4. In doubt **seek advice** - Role Model/ Guru; **correct course**/ action plan
5. **Self actualisation** – **Implementation** of Knowledge; **Skill - Mastery**
6. ***Transformed, individual - Organisation***


I refuse to go back to
the old me. I'm becoming
a better person using
my past experiences as
lessons.

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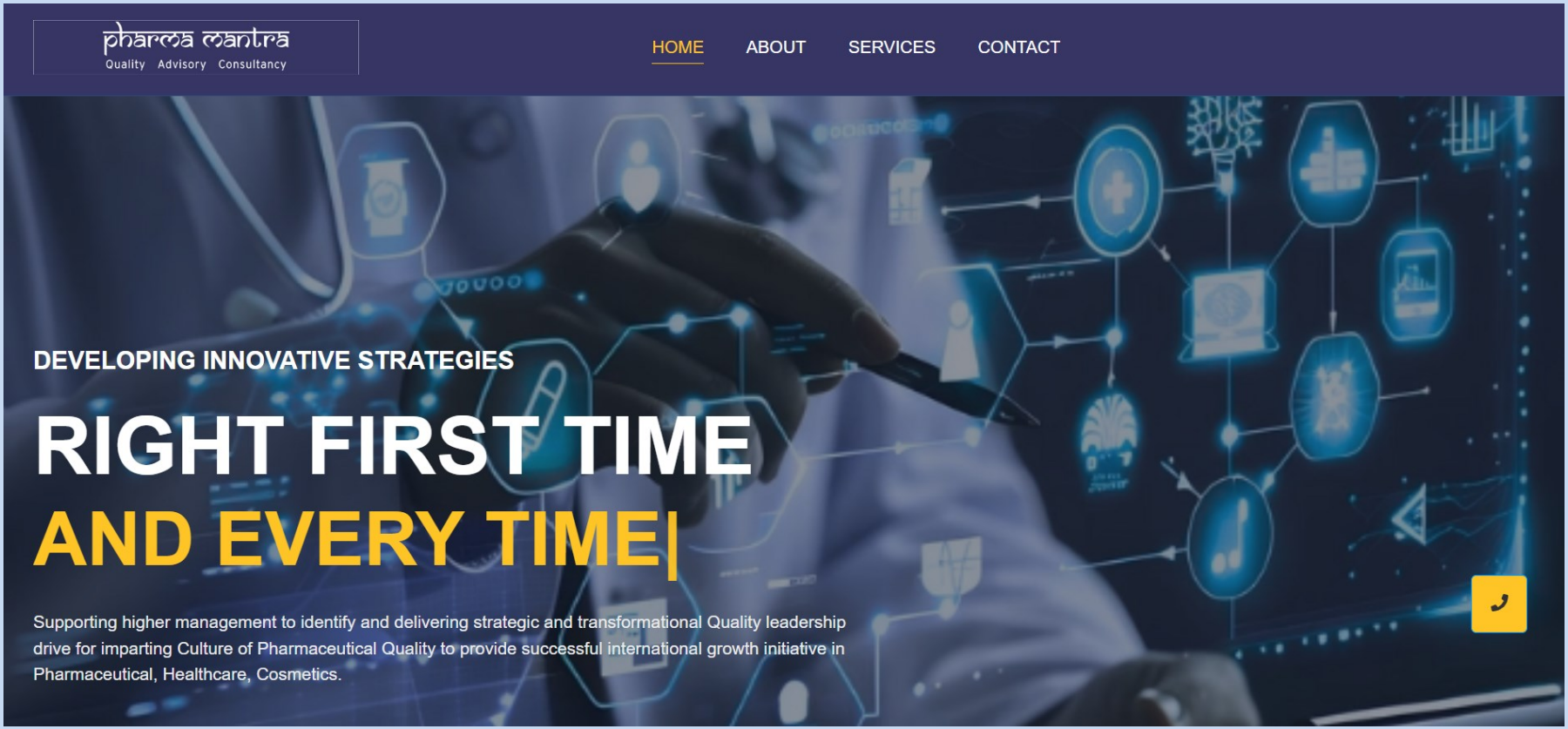

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Role of Founder of PharmaMantraTM- Since Aug' 2017 –

Enabling the process to facilitate the management at Board and Shop-Floor level to identify and help delivering strategic and transformational Quality leadership drive for imparting, *Culture of Pharmaceutical Quality*. Worked at global organisations across continents/ geographies to provide successful international growth initiative in Pharmaceutical, Bio-Pharmaceuticals, Herbal, Device, Healthcare, Cosmetics industry.

Mentoring, Training & handholding the site and corporate management to support and bring in the desired SOC – State of Control.

Deliverables and Achievements –

We have experience in on-site and off-site assessment of the GXP data. Provide effective compliance strategy and QIP (Quality Improvement Plan) for Quality Management. Services provided to various clientele- API- Intermediates, API/ DS, DF, Devices, IT- software, AI-ML. Since, March 2020; we adopted seamlessly to go virtual & did CGMP activities due to the exigency caused due to Covid-19 Pandemic. During subsequent Lockdown we provided the remote review & CGMP assessment for developed Markets like USFDA, EU region – QMS Review, Batch Record Review and Release of the Sterile Finish Products. Proposed the WL Remediation strategy, Plan and CAP. Virtual CGMP Audit and due diligence. Virtual Training and mentoring and advisory for Global corporations.

https://www.pharmantra.expert/services/

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Udaykumar K. Rakibe, M.Pharm. Ph.D. MBA

ABOUT US

Udaykumar is a quality professional with a dynamic career steering organization through complex Quality & Regulatory challenges, transitions, building an empowered and talented workforce in the cross-cultural environment within highly competitive products and regulatory environment.

In Year 2006, as Director – Quality Assurance, he was mandated and given the task to execute and spearhead the proactive remediation at Ranbaxy Lab. Ltd. Subsequently since Daichii Sankyo takeover, he was made Head, India and Asia Quality Operations and overseeing the state of control. In late 2011 he was recruited by Intas Pharma Ltd. to create a self-sustaining quality management system and enhance inspection readiness. Further, in 2013 he was hand-picked & recruited by Wockhardt Ltd., as Senior Vice President – Quality, to turn around the Quality Management, lead and manage the remediation of Quality initiatives. In 2021 Morison Sri Lanka, brought him on board as Chief Quality Officer-CQO, to achieve and realize the vision of the MD & Chairman to have a State-of-the Art facility at Homagama, Colombo. He has represented the Organisation as Quality Head and prepared, presented and attended the regulatory meetings with IAG/ MHRA/ IMB/ USFDA at London and Washington respectively. As a Quality professional, has performed 400+ Audits and faced 500+ regulatory audits.

He began his career in Quality function as an Executive In-process QA and then mov different levels and organization spanning 27 plus years of hands-on and hard-core experience in the pharmaceutical regulatory environment. He has gained the domain experience in Quality & Operations, specifically focusing and leading the Quality & Regulatory remediation in last 12 years (2006-2017). He has worked for a decade in

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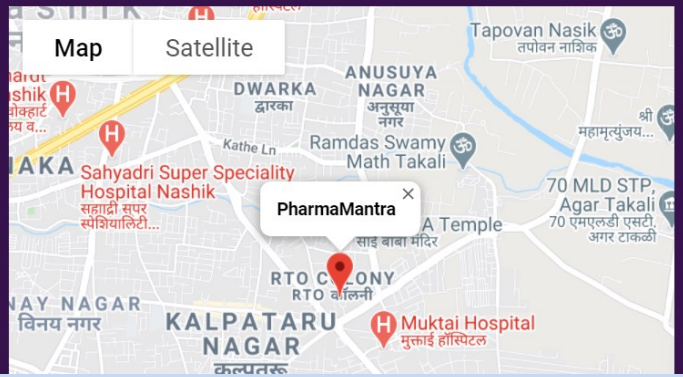

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Subject