

# Curriculum Vitae

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

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**Nationality** - India  
**Languages known** - English, Hindi, Marathi  
**Date of birth** - 31<sup>st</sup> July 1968

## Academic Qualifications

**India, University of Pune (SPUP),** B.Pharmacy, M.Pharmacy (Pharmaceutics), MBA

**India, University of Aurangabad, Dr. BAMU (UDCT),** Doctor of Philosophy (Pharmacy), Ph.D.

## Summary

A highly motivated result oriented professional with three decades plus domain experience in the Pharmaceutical Quality & Operations Management in Regulatory GXP/CGMP arena. 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.

Proven expertise in defining organizational structure for Quality Management and align Quality function with the Business objectives/ goals. Providing catalyst to optimize performance, enhance productivity, drive compliance, deliveries along reduction in cost of quality/ improving profits.

Improved the quality metrics & KPI (Key performance indicator), Timely launch of new and existing product deliveries to market, focussed on Organisational Team building & control on attrition rate. Identified and streamlined desired QS (Quality System) – for Gap Assessment, Harmonisation and Digitisation.

Lead and spearheaded the task of developing, formulating and implementing a Global Remediation Action Plan & Strategy. An accomplished professional, supported organisations in steering through challenges of FDA Actions- Warning Letter & Import Alert. Designed and proposed the remediation and formulation of desired Corrective Action Plan (CAP). Designed, commissioned state-of-the-art Quality Control Laboratories & manufacturing facilities API, Intermediate, DF, Devices- such as, Injectables (PFS, Vials, Ampoules), OSD, SoftGel, Semi-Solids, Liquid Orals, Herbal. Created self-sustaining Quality management Systems and prepared site and management for FDA, EU, WHO pre-qualification inspections. *In past 2 decades plus faced and participated in 450+ Regulatory Audits, and in the corporate role globally performed 400+ CGMP/ due diligence Audits.*

### Value –

- Trustworthy, Truthful, Honest
- Dependable, committed to excellence

### Skills –

- Instilling Culture of Pharmaceutical Quality
- Mentorship & Leadership, Articulate Communicator, Listener & Influencer
- Strategic thinking & task orientation for remediation activities

### Deliverables –

- Lead, mentored large teams, Budget for sites & 10+ direct reports
- Building Strategic planning and execution of plans, project management
- Planning and Leading regulatory and vendor/ supplier audits
- Review and development of Quality Management Systems-API,DF,R&D,BA/BE,Toxicology,Device
- Developing and Launching new products with 3<sup>rd</sup> party R & D and operations team
- Training and development, Organising workshops, Guidelines in GXP domain



## Advisory & consulting Experience

### **Role of Founder of PharmaMantra™- 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.

### **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

### **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

## **Professional Experience – Quality Operations**

**Highlight** - Providing the desired support for steering organization through complex Quality & Regulatory challenges, remediation, transitions. Help identify and build an empowered Quality & Operations Team which is capable and empowered to deliver results within highly competitive products and regulatory environment. Effective implementation of Digital-Quality Systems including oversight of IT applications.

By virtue of working in responsible position as Head of Quality gained experience in -

- Instilling the Culture of Pharmaceutical Quality
- Regulatory Meetings with FDA & IAG/MHRA, communication, response to agency
- Audit management, response drafting, critical review and CAPA presentation
- Formulated the regulatory Strategic pathway for remediation/ QIP
- Mentorship & Leadership, Reorganisation of the Quality at Site & Operations
- Review of organisation resources – Manpower, Capital, Revenue
- Training - Corporate & Sitewide, (QMS, GMP, Data Integrity)
- Management Review – Resource and critical risk for mitigation
- Review and analytics of the Quality Metrics, Contract Manufacturing and Tech Transfer
- Vendor development – DS(API), DF (Drug Formulation) for developed markets

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### **Morison Limited, Colombo, SriLanka | Chief Quality Officer | Dec'2021 to Jan'2023**

#### **Role & Responsibility –**

To provide the strategic and executive leadership to the R&D, BD, SCM, Site Operation & the Quality Function to implement the desired QMS, Regulatory Strategy for EU/ Eudralex/ PIC/s Compliance.

#### **Contributions & Achievements –**

Commercialised on 26<sup>th</sup> May' 2022 the OSD and Liquid oral products, a milestone achievement. Performed resource assessment, quality training, focus on new products, investigations- RCA/ CAPA, scale-up and increasing batch size, Quality Excellence and Quality Culture.

Initiated, executed the process of –

1. **Training-** Initiated Virtual, Classroom Trainings, conducted Train the Trainer Workshop, Host the Regulatory Inspections, 40 plus QS procedures,
2. **Management Review** as SQC-Site Quality Council, Quality Board, with MD, HODs.
3. **QMS-** for EU, US-FDA.
4. **CGMP Gap** assessment and **remediation** to give an effective yet simple QMS.
5. **Re-structuring** of Quality Function for strengthening Compliance.
6. **Quality Plan**, helped board/ management to carve out a, 2022-2025.

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### **Wockhardt Limited | Senior Vice President – Quality | 16<sup>th</sup> Aug 2013 to 31<sup>st</sup> Jul2017**

#### **Role & Responsibility –**

Was handpicked by Chairman to streamline the Quality Function and implement the desired Remediation Strategy for FDA and MHRA - post Import Alert and WL issued to Wockhardt in 2013.

#### **Contributions & Achievements –**

Worked with internal stakeholders, 3<sup>rd</sup> parties like Lachman, PWC, Step Change, Quantic for ensuring an effective remediation. Being a **SPOC- single point of contact**, responsible for regulatory communication, meeting with regulators (USFDA & IAG/ MHRA). Extensively worked on re-structuring of Quality Function for strengthening Compliance; provided leadership to 20+ direct reports, 1200 indirect (Biotech, Devices, DF, API, BA/BE, R&D-QA). Started and conceptualised the Office of Global Quality & Lead the Quality initiatives. Faced successfully 56+ regulatory and unannounced FDA and MHRA audits in period 2013 till 2016.

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**INTAS Pharmaceuticals Ltd. | Senior Vice President – Quality | Nov 2011 - Aug2013**

**Role & Responsibility –**

Mandated by the Vice Chairman and MD for strengthening the QMS at two sites (DF/ API) – manufacturing Oncology and General Products (oral solids and Injectable).

**Contributions & Achievements –**

Performed the gap assessment of the QMS and recurring product failures. Prepared an action plan and strategy remedy the ANDAs with desired CAPA. Led the entire team – during Audits by US-FDA, MHRA/EMA, ANVISA, TGA, HC, MHLW. Developed and executed Quality Improvement (QIP) & road map to achieve robust QMS.

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**Ranbaxy Labs Ltd. | Director-Head India & Asia Quality Operations | Aug2006-2011**

**Role & Responsibility –**

Identified and bestowed with the responsibility as a part of the alignment and transition team from *Ranbaxy to Daiichi-Sankyo*. Head of Quality of 8 DF sites in India and Asia region (China, Malaysia, Vietnam) reported directly. Sites supplied to regulated markets.

**Contributions & Achievements –**

Reorganised and led a team with large span of control with 9 direct reports and about 700 strong Team. Executed Quality workshops & training programs for senior quality personnel. Trained and prepared teams to face numerous regulatory Audits from 2006 to 2011. Performed gap assessment and revamped the QMS in QC laboratory and Manufacturing operations. Pioneered the QMS digitisation successfully. Responsible for driving *Tracwise®*, *Documentum®*, *LMS®*, Stability module. Conceptualised and commissioned a state-of-the-art Microbiology and QC lab. Initiated Management Review (MR), Quality Review Board (QRB), and CAPA management at manufacturing sites.

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**Ranbaxy Labs Ltd. | Associate Director Corporate Quality | Nov 2000 to Aug 2006**

**Role & Responsibility –**

After nine years in site quality operations, working at various levels; I was tasked by Director Quality Ranbaxy – to and help create a Global QMS for the globally diversified Ranbaxy. In the Corporate Quality role, pioneered the concept & implementation of corporate quality guidelines (CQG).

**Contributions & Achievements –**

At Ranbaxy Global Quality – managed various quality teams working in R&D QA, facilities for DF & API. Reorganised and led a team with large span of control with 7 direct reports and about 24 strong Team. Responsible for the review and approval of data package – by R&D Quality Teams employed in review of Formulation and Analytical Development, Clinical and BE data, and facilitating Product Tech Transfer. Managed the annual Audit Program of DF & API manufacturing sites (conducted about 400 plus audits). Training Workshops, Developed the QA Team, due diligence of sites worldwide, East to West.

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**Gland Pharma Ltd. | General Manager Quality & regulatory Affairs | Apr 1999 to Nov 2000**

**Role & Responsibility –**

Was recruited by Chairman to develop site Quality & Regulatory Functions – Procedures, People, Process for ongoing US FDA compliance, for a world-class aseptic manufacturing facility.

**Contributions & Achievements –**

Reorganised and led a team with large span of control with 5 direct reports and about 150 strong Team. Reorganised the Quality & Regulatory Functions including the QMS, Documentation, People, Validation Protocols, Procedures, and facilitated to improve compliance, efficiencies at site. Participated and led the regulatory and Client Inspections (Schering Plough, Hoechst, Merind/ Wockhardt).

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**Dabur Pharma Ltd. | Manager Quality Assurance | Apr 1997 to Mar 1999**

**Role & Responsibility –**

Identified by MD and asked to lead a team of Quality for Injectables (oncology & General products) and Herbal drugs. Reorganise QMS for complying regulatory Audits – for the Injectable site & oral solid dosage forms.

**Contributions & Achievements –**

Reorganised and led a team with large span of control with 5 direct reports and about 100 strong Team. Was instrumental in new projects execution - commissioned Oncology/ General products sterile product Mfg facility, including soft-gel facility, Herbal facility, Real Fruit Juice Launch. Performed gap assessment and prepared the oncology Injectable site & personnel for EU & FDA inspection. Successfully lead the OGYI-Hungary, MCC (S. Africa) and WHO inspections.

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**Ranbaxy Labs Ltd. | Executive IPQA | Oct 1995 to Mar 1997 &  
Glenmark Pharma Ltd. | Executive QA | Feb 1991 to Oct 1995**

**Role & Responsibility –**

In-process Quality and Validation of Process, Plant and People.

**Contributions & Achievements –**

Was part of the formative team at new site and involved in the scale-up and commercialization of new products. Responsible for the manufacturing, process validation of Oral Solids and release to domestic markets. Worked on the US & Europe Exhibit batches and filing in US FDA and MHRA/ EU markets. Involved in setting up of QA system and QMS at site. Laid down procedures and formats for Process & Equipment validation.

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**Significant Awards/ Interests**

**Professional**

- 2010 Ranbaxy Labs. Ltd. Long Service Award, 10 Years
- 2015 Wockhardt Ltd. Chairman Leadership Award
- 2015 World Quality Congress, 100 Most Influential Quality Leader
- 2019 National Congress & Awards for Exports & Packaging, Most Influential Quality Leader
- 2020 World Logistics & Supply Chain Congress Awards, Most Fabulous Leader, Pharma Industry
- 2024 Certificate of Honour conferred by Quality Learner, India, for 200Plus Webinars

**Academics**

- 1991 Mahindra Talent Scholarship, 1<sup>st</sup> ranker M. Pharmacy Sem-II, Rs.7000 award

**Interest/ Others**

- 1986 Air N.C.C, A Certificate, Glider Pilot- Flying Licence, ATC Camp (10 days)
- 1987 Air N.C.C, B Certificate, ATC Camp (10 days)
- 1986-88 Captained College Football Team, field & track athlete
- 1991-95 Organised and Captained Glenmark Cricket Team
- 2017 onwards, consciously learning & working on self-improvement, Mind, Body & Soul.

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**Publications & Presentations**

**Articles Published**

1. A Validated Stability Indicating High Performance Liquid Chromatographic Method for Olanzapine. Latin American Journal of Pharmacy, 36, 1462-1468.
2. UPLC, HR-MS and in-silico tools for simultaneous separation, characterization and in-silico toxicity prediction of degradation products of atorvastatin and Olmesartan. Acta Chromatographica.



3. Stability indicating validated HPLC method for simultaneous quantification of Nitazoxanide and Ofloxacin in pharmaceutical dosage form. Latin American Journal of Pharmacy.
4. LC and LC-MS/MS studies for the identification and characterization of degradation products of Acebutolol. Journal of Pharmaceutical Analysis. Manuscript ID: JPA-D-17-00164R1.
5. A Validated Chiral High-Performance Liquid Chromatographic Method for Enantiomeric Separation of Glycidyl Butyrate on Cellulose based Stationary Phase. International Organization of Scientific Research (IOSR) Journal. Manuscript ID: E 84043.
6. Quality by Design: Design of experiments an approach for HPLC assay method of fixed dose combination product-Fexofenadine and Montelukast. Journal of Chromatographic Science Manuscript ID: JCS-17-266.
7. Pharma Now a Global Pharmaceutical Publication, has on boarded me as advisor and planned for 5 articles in 2025. Details shall be provided on request.

## **Publications & Presentations**

### **Training Workshop, and Conferences:**

1. Current Situation of Ethnomedicine – Medical Knowledge: Promotion, Protection and conservation, Resource Person, Guest of Honour, National 5 Day Seminar at Govt. College of Pharmacy, Aurangabad, 10th-11th Feb'2016.
2. UBM, Workshop, Speaker, Advisor, Panellist "Investigations, Management of CAPA Challenges and Case Studies", Sahara Star, Mumbai, 25-26<sup>th</sup> May 2017.
3. SrikrishnaPharma,Workshop, "Investigations, CAPA in the Pharma&API Mfg., HYD. 29-30th May'2017.
4. Evolving US Regulatory Expectations, Resource Person – Dr. Ajaz Hussain, Ph.D. Organised, Facilitator in collaboration with Y.B. Chavan College of Pharmacy- Aurangabad, the National Level Seminar held at The Taj, Aurangabad, 23rdJuly'2017.
5. Resource person and Guest of Honour, a national level Seminar on date 26th Sep'2017 at Dr. M.S. Gosavi College of Pharmacy, Nashik-5.
6. Competence Pre-Requisites for Embarking in Pharma Career, Resource Person and speaker at National Level Conference at S.G. Sapkal Pharmacy College, Anjineri, Nashik, on 11thNov'2017. Inaugurated and assessed the poster presentation, more than 50 posters were presented from different Pharmacy colleges in and around Nashik District and valedictory function.
7. National Level Seminar on "Recent Trends in Pharmaceutical Excipients", Speaker and resource person. The conference held on 24th and 25th of November, 2017 at M.V.P Samaj's College of Pharmacy, Nashik-2.
8. EBM-Advisor/Speaker/Panellist,"Challenges–Pharma Project Mangt", Orchid, Mumbai, 8-9thMar'2018.
9. "Exploration of Herbal Domain: Past, Present and Future of India on Global Map", Speaker and resource person at 2 Day National Conference, "Ethnocon-2018", on 23-24thMarch'2018.
10. EBM-Advisor/Speaker/Panellist,"PharmaMfg & Auto.Convention2018",Westin,HYD,22-23<sup>rd</sup> June'2018.
11. EBM-Advisor/Speaker/Panellist, "Investigations & CAPA", Sahara Star, Mumbai, 11-12<sup>th</sup> Oct'2018.
12. Viva College of Pharmacy – Speaker, advisor, "Biologics & Biosimilars" Virar, 9thFeb'2019.
13. EBM-Advisor/Speaker/Panellist,"2ndPharma Project Mangt",Orchid, Mumbai,21/22<sup>nd</sup> Feb'2019.
14. Techno Business Conferences- Workshop, Course Director, "Workshop on Technical Writing - Investigations and responding to 483's, Audit observations", April-May 2019 -Chandigarh, Mumbai.
15. Hetero- Workshop, "Investigation and CAPA", Vizag & HYD August, 2019.
16. EBM- Speaker, Panellist, Pharma Packaging Summit/Industry 4.0, Novotel, Mumbai, 29-30<sup>th</sup> Aug'2019.
17. Abbott- Workshop, "Principles of ALCOA/GDP/Data Integrity, Baddi/ Mumbai/ Goa, Sep/Nov' 2019.
18. Virtue Insight, Panellist, "Industry 4.0, automation and digitisation in Pharma", Mumbai, Sep'2019.
19. National Congress & awards – Keynote speaker, "Challenges for Regulatory & Quality", 20<sup>th</sup> Nov'2019.

20. CPhI-Pmec, speaker, panel moderator, Inopak Theatre, "Pharm Industry – Quality & Regulatory Challenges" Greater Noida, 26-28<sup>th</sup> Nov'2019.
  21. Bliss GVS- Workshop, on-site, Cleaning Validation -Reg/Ind perspective/Compliance". 14<sup>th</sup>Mar'2020.
  22. EBM- Speaker, "Quality, Comprehend the changing elements QA/QC Pharma", 14-15<sup>th</sup>May' 2020.
  23. EBM- Advisor/Panellist/Speaker "Advanced Pharma Quality Forum", 8-9<sup>th</sup> Oct'2020; Mumbai.
  24. EBM- "Accelerating India's Pharma Supply Chain: Quality/Compliances/Operation", 21-22<sup>nd</sup> Oct' 2020.
  25. WHO- "Materials Management including Warehouse Management", 27th Nov' 2020.
  26. ET- Panellist/Speaker, Drug Delivery and Formulation Summit, "Towards innovation: creating new value and adapting to shifting landscape", the ET 27th Nov'2020.
  27. EBM- Advisor/Panellist/Speaker "An online event for APAC Region by the FDA Industry CSA Team and GAMP GPG Data Integrity by Design co-authors, February 18th & 19th 2021.
  28. WHO- Mentoring Programme- For more than 30 API and DF manufacturing facilities in India, Feb'2021.
  29. Blue Tech, Moderator-Panellist, "India Biopharma Leaders Conclave, Mumbai, 21-22<sup>nd</sup> May2020.
  30. EBM- Advisor/Panellist/Speaker, Pharma Audit Readiness, Mumbai July 29-30th, 2021.
  31. EBM- Advisor/Panellist/Speaker, Cleaning Validation an overview, Novotel, Mumbai 21-22<sup>nd</sup> Oct'21.
  32. WHO Mentorship programme, 5 Indian API & Pharma organisations, FDA-6 QS, Oct-Nov' 2021.
  33. Morison, Colombo, Sri Lanka, Training Workshop- Train the Trainer, Hosting Regulatory Inspections & a weekly virtual training on CGMP/SOP30+topics, Jan'2022 to Jan'2023.
  34. EBM-Advisor/Panellist/Speaker,3<sup>rd</sup> Annual Pharma GMP/ Quality Management, Mum,2-3<sup>rd</sup> Mar'2023.
  35. Blue Tech, Course Director, Hosting Un-announced audits, Kohinoor, Mumbai,17-18<sup>th</sup> Mar'2023.
  36. EBM-Advisor/Panellist/Speaker, 1<sup>st</sup> Pharma Regulatory Conclave 2023, Hilton, Goa, 5-6<sup>th</sup> Jul'2023.
  37. Kilitch Healthcare Ltd., Rabale, Maharashtra, DI, Hosting Reg Inspections, EM, Aseptic techniques and behaviour in APA, Jan-June'2024.
  38. Quality Risk management, PULSE Series of training programmed supported by PharmaState Academy. Virtual, August' 2024.
  39. Data Integrity CaseCon 24-25, presentation and Panel Member at HITEX Exhibition Centre, HYD, organised by – Messe Muenchen, IIM Sirmour, PharmaState Academy. 28<sup>th</sup> Sept' 2024.
  40. Kopran DS Mfg Facility, Mahad, Maharashtra, Train the Trainer, CSV, Hosting Reg Inspections, Feb'2025.
  41. EBM-Jury/Advisor/Panellist/Speaker,5<sup>th</sup>Annual Pharma GMP/ Quality Management, Mum, 24-25<sup>th</sup> April' 2025. Spoke on the "Pharmaceutical Quality Risk management". Also, participated as Jury Invitee, at the Gala Pharma Quality Awards Night, 25<sup>th</sup> May' 2025, Hotel WestIn, Mumbai.
  42. 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. 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.
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