Dr. Pushpinder Paul

Principal QMS Auditor-Quality Compliance & Excellence (QCE)

A technically astute, vigilant, and ardent individual with over 18 years of prodigious experience in Quality Control, Quality Assurance, Regulatory Affairs & Regulatory Compliance, Internal & external Audits, Pharmaceutical Manufacturing, Corporate Quality Assurance, Remediation, Green Field Projects Clinical Research and Clinical Data Management. Seeking to pursue a career in the upper echelons of pharmaceutical world, which calls for extremely high levels of leadership qualities, Compliance and technical abilities, with the goal of spearheading Quality Assurance & Regulatory Compliance in Pharma/Medical Device Industry and enhancing the company's productivity and reputation.

pushparyan27@gmail.com

+919099982213/9106396200

Nalagarh, India

linkedin.com/in/dr-pushpinder-paul-ab333118

SKILLS

Quality Assurance | Regulatory Compliance | Internal & External Audits | Pharmaceutics and Pharmacovigilance | CMO/CRO/CDO Management | Product Verification and Validation | Clinical Research & Clinical Data Management | New Product Development | Clinical Trial Management | Supplier Qualification & Portfolio Management

KEY STRENGTHS

Quality Management:

Offering profound knowledge and experience in Quality Assurance activities in the pharmaceutical & Medical Device manufacturing environment. Comprehensive knowledge of and broad experience in Quality Assurance, Validations, QMS Auditing and Regulatory Affairs. Thorough knowledge of protocols, procedures and methods for conducting a wide range of manufacturing, research, process, system, and regulatory-related audits.

Regulatory Compliance:

Advanced working knowledge as per ISO 9001,14001,45001,17025,22000,13485, ISO2716: 2007, 17021-1:2015, 19011:2018, ISO 15378 ISO/IEC 42001:2023 ISPE & NABH Lead Auditor and IRCA United Kingdom & Quality Council of India-Registered Principal Auditor. Advanced knowledge of regulatory affairs, Clinical trials, FDA guidelines, Good Clinical Data Management Practice (GCDMP), ICH-GCP, GLP, cGMP, SOPs, and CMC Regulatory Affairs.

Project Management:

Possess the ability to successfully manage and deliver sizable projects within my own area of responsibility by identifying key milestones and resource requirements. Provide administrative, Quality, regulatory & technical expertise to achieve project goals and objectives while honouring the project constraints, typically scope, time, and budget. Oversee all the tasks for allocated projects ensuring adherence to regulatory guidelines, management instructions and providing supervisory functions for direct reports.

Team Management & Collaborations:

Align the team to the vision and strategy of the organization. Understand employees' short term and long-term goals, map them with organizational goals and create and communicate larger overlaps. Demonstrate leadership to the team through training, coaching, motivation, and the conduct of performance management process. Maintain strategic relationships and partnerships within and outside the organization to fully support the achievement of the functions' goals and objectives.

CERTIFICATES

-Six Sigma yellow belt certification from MSME-technology development centre, Agra.

-Registered Principal Auditor (QMS) with IRCA-UK (International Register of Certified auditor).

-Registered Principal Auditor (QMS) with NBQP/QCI (National Board for Quality Promotion/Quality Council of India).

-Certified ISO 9001-2015 QMS Lead Auditor from TUV Nord Pune (IRCA Approved, Certification No.- 12808) and ASCB (Accreditation Service for Certifying Bodies, United States).

-Certified ISO 45001-2018 Lead Auditor from ASCB (Accreditation Service for Certifying Bodies, United States).

-Certified ISO/IEC 17025:2017 Lead Auditor from Punyam Academy (Certificate No. PA/2019/100095)

-Certification for GCP Inspection/Audit at clinical Investigator Site by "The Global Health Network".

- Six Sigma Master Black belt certification from Expert rating Pvt. Ltd., An ISO 9001 certified Organization.

-Certified ISO 13485-2016 Lead auditor from British Standard Institution (IRCA Approved).

-Certified ISO 14001-2015 Lead Auditor from ASCB (Accreditation Service for Certifying Bodies, United States).

-Certified ISO 22000:2018 Lead Auditor from Punyam Academy (Certificate No. PA/2019/100200)

- Certified vendor cum Internal Auditor from CEI (Corporate events India).

-Total Quality management certified professional from Expert rating Pvt. Ltd., An ISO 9001 certified Organization.

-ISPE Certification for "GMP Auditing for the Pharmaceutical Industry".

-ICH-GCP &GCP-ASU certification to, "conduct GCP studies and auditing GCP sites" from Indianvaidyas.

-HACCP & ISO 22000:2018 Certification from Quality Fusion India.

-Food Safety Supervisor certification on advanced manufacturing from FSSAI.

-ISO 22000 internal auditor and skill development certification as per ISO 19011-2018 from Quality Fusion India.

-ISO 17025:2017, NABL Accreditation process, FSSAI Recognition of Laboratory/Food Safety & Standard Regulation, 2011 from Quality Fusion India.

- Food Safety and Standards (Packaging) Regulation 2018, Food Safety and Standards (Labelling and display) Regulation 2020, Advertising & Claim Regulations 2018, Organic Foods Regulations 2017 and Food Recall Procedure Regulations 2017 certification from Quality Fusion India.

- Food Safety and Standards Regulations 2016 and 2018 certification from Quality Fusion India.

-MDSAP Certification from GMP Pharm quit and RQM+ Academy.

-Lead Auditor Certification on Artificial Intelligence Management System based on ISO/IEC 42001:2023 from TUV SUD.

-ISO 22716:2007 lead auditor certification from Punyam Academy India.

- ISO 17021-1:2015 auditor certification from Punyam Academy India.

-ISO 19011:2018 auditor certification from Punyam Academy India.

-ISO 15378 auditor certification from Punyam Academy India.

-GCP Auditor Certification course from NB Science United Kingdom.

WORK EXPERIENCE

Principal QMS Auditor-Quality Compliance & Excellence (QCE)

10/2022-Present

- Director of Quality Compliance & Excellence and Principal QMS Auditor.
- Expertise in performing the gap analysis of Formulation, API, Excipients & Packaging Material manufacturing units with respect to the various regulatory standards like USFDA, MHRA, EU, PICS, TGA, ANVISA, WHO etc.
- An expert in various processes like aseptic area qualifications, validations, Media Fill, analytical techniques, analytical method transfer, analytical method validation, process validation, Water system Validation, HVAC Validation and QMS Handling.
- Registered Principal Auditor with Quality Council of India.
- Registered Principal Auditor with International Register of Certified auditors. (IRCA), United Kingdom.
- Performed around 100 GMP audits as Lead Auditor.
- Audit the facilities in line with Various Regulatory norms as intended by Sponsor.
- Perform GAP assessment as per Guidelines for which Client company seeking the certification.
- Guide plant teams for up gradation/build up the system to bridging the GAP/Remediated the identified discrepancies.
- Implementation of Quality Management System.

Head Quality & Regulatory (GM-QA, QC, RA, Clinical & NPD)

Advanced MedTech Solutions Pvt. Ltd.

04/2022-10/2022

- Work as Head Quality & Regulatory for Advanced MedTech Solutions Pvt. Ltd. to ensure adherence with ISO 13485 and EUMDR requirements for various range on medical devices viz. wound closures, cardiovascular, Endo mechanical etc. to achieve quality objectives.
- Compliance to all the regulatory and statutory requirements to ensure business continuity.
- Ensure timely delivery of compliant Medical Device products to all markets.
- Ensure timely submission of medical device technical Files/dossiers to Domestic and International Markets.
- Ensure smooth execution of New Product Development projects to develop business solutions and meet regulatory requirements. Ensure and monitor quality health of the organization through routine quality metrics, Internal audits and trainings.

Sr. Manager Corporate Quality Assurance & Regulatory Compliance

Sentiss Pharma Pvt. Ltd.

04/2017 – 03/2022

- Work as Sr. Manager Corporate Quality Assurance & Regulatory Compliance for Sentiss Pharma and CRO/CDO/CMO units by ensuring adherence with ISO 9001:2015, ISO 13485, ISO 14001 and ISO 45001 requirements to achieve quality objectives.
- Lead Pharmacovigilance projects to develop business solutions and meet regulatory requirements. Ensure and monitor quality health of the organization, contract manufacturing locations (06 No.), contract testing labs (30 no's) and CRO/CDO through routine quality metrics and surveillance auditing.
- Monitor quality systems to provide recommendations on compliance risks to QA management and identify opportunities for improvement. Perform Root Cause analysis, Impact assessment and investigation review related to all sites (Sentiss & CML). Support the creation and management of SOPs for all aspects of manufacturing and quality management.
- Facilitate Quality Oversight of 8 CDO/CRO and 6 Contract Manufacturing Locations for Sterile and oral products (Compliance & Release of products) and ensure compliance at manufacturing site(s) w.r.t regulatory requirements. Establish a state-of-the-art facility through monitoring, in-process control and

release of batches for Contract Manufacturing Locations.

- Manage planning and execution of management Quality Review meetings. Review and approve QMS elements (OOS, OOT, OOL, OAL, Deviations, Investigations, CAPA, Change Controls and Market Complaints).
- Provide leadership and key negotiations with vendor contracts and manage vendor selection process based on company goals and company risk factors. Contribute to vendor qualification (RM, PM & GMP Consumables), CML, CDO/CRO and CTL Qualification/Requalification.
- Support the installation, qualification, validation of new technology/equipment. Qualification, validations, media fill and process validation activities of the sterile facility. Lead validation team for preparing & reviewing URS, FAT, SAT, IQ, OQ, and PQ of different equipment's.
- Handle the entire gamut of functions related to Clinical Data Management and maintain a high level of knowledge regarding current industry and regulatory trends and requirements.
- Act as Management Representative for ISO/Regulatory audits at all units. Build a diverse team of talented and motivated professionals by providing Internal/External Auditing & cGXP training. Ensure that organizational systems (processes, technology, people, and schedule) are in place to support the accomplishment of short and long-term business objectives.

PREVIOUS EMPLOYMENT HISTORY

Glenmark Pharmaceuticals Limited, Dahej as Manager Operations and QMS Compliance (Sterile & API unit) (2014 - 2017).
Responsible for New Facility Qualification, Operation Management, Validations, QA Compliance & Internal Auditing in Sterile & API Facility.

Ranbaxy Laboratories Ltd. as Sr. Executive Operation and QMS Compliance (2013 - 2014)
Responsible for New Facility Qualification, Validations, Investigations, QA Compliance & Internal Auditing in Sterile Facility.

OCPL, Aurangabad unit as Executive Operation and QMS Compliance (2011 - 2013)
Responsible for Production, Validations, Investigations, Documentations & Internal Auditing in sterile Facility

WOCKHARDT LIMITED, Ankleshwar unit as Officer Sterile Operation & Validation (2010 - 2011)
Responsible for manufacturing of sterile products. Documents Compliance and Validation.

NECTAR LIFE SCIENCES LTD. as Sr. Chemist in Sterile Operations & Documentations (2009 - 2010)
Responsible for manufacturing of sterile API and documentation.

Modern Diagnostic Centre, Mohali as Biotechnologist and lab chemist (PT) (2006 - 2009)

ACHIEVEMENTS

Conducted more than 100 First Party/Second Party/Product audits which include vendors audits, contract testing labs, CROs, CMOs, Product-specific audits, Water system audits, etc.

Presented 6 Research papers at international level& Published 11 research papers in international journals (ICB-2012, ICRASE-2012, Biofest-2012, DNA-2012 & Accelerating biology 2013 ISRJ, GRTJ, IJPRD, IJSR, Helix International journal).

MEMBERSHIP

Standard member of Parental Drug Association (PDA).

Standard member of International Society of pharmaceutical Engineering (ISPE).

Pharmaceutical Scientist Member with Royal Pharmaceutical Society UK.

KNOWLEDGE PURVIEW

Major Regulatory Audit Experience

- USFDA | MHRA| WHO-GMP | EU- GMP | PMDA | TGA | KFDA/PICS/ Russian and Ukrainian Regulatory etc.

Validation/Qualification Experience

- Facility qualification, Green Field projects, Equipment's qualification, Water System (PW, WFI, PSG) Qualification, Utility (Nitrogen/Air) Qualification. etc.
- Steam heat sterilizer & Dry Heat sterilizer validation, SIP Validation of sterile equipment's.
- Process Validations of sterile/API /Oral and solid Products, Process simulations SCDM and Validation of HVAC system, LAFs, GCUs, DPB etc. Cleaning validations, Fumigation validations and Filter validations of sterile products.

Quality Management System Experience

- Total Quality Management System certified professional from Expert rating.
- Lead Management Review & Quality review board meeting as Management Representative (MR) for periodic review of process performance and product quality of pharmaceutical quality systems.
- Review and Approval of Deviations, Change controls, Investigations and CAPAs.
- Review of Annual product review reports & Annual Bioburden, EMP reports for any excursion. BET evaluation reports of the process and equipment's.
- Manage Internal and External/Regulatory Audits.
- Review and Approval of Validation master plan and Site Master.
- Review and finalization of audit responses and submission of same to regulatory agencies.

Products Validations Experience

- Paliperidone Palmitate Sterile, Meropenem Trihydrate Sterile, Imipenem Sterile, Doripenem sterile, Biapenem Sterile, Cilastatin Sodium sterile, Sodium carbonate/ bicarbonate sterile, Ceftriaxone, Cefepime Cefuroxime and Cefotaxime Sodium Sterile
- Sterile Ophthalmic, Injectables and Inhalations of various range
- Liquids, Tablets and Capsules of various range
- Food and Nutraceuticals products
- Medical Devices of various range viz. Wound closures, cardiovascular, Endo mechanicals, Ophthalmic etc.

Investigation Skills and Experience

- Lead investigation team as Core member in operational and quality incidents, failures findings and effective CAPA implementations.
- Trained on Effective Use of Investigation techniques such as Why tree analysis, Failure mode and effect analysis, Fault tree analysis, Fish bone diagrams etc. to solve and find root cause of the quality and operational failure issues.

EDUCATION

PhD Biotechnology
Singhania University, Rajasthan
2017,

- **Project:** "Isolation & identification of vibrio species by multiplex PCR and antimicrobial activity of various fruits against these isolates".

Executive MBA in Operation Management
KSOU Bangalore, Karnataka
2012,

P.G. Diploma in Nano Biotechnology
Life Science Foundation India *2013,*

P.G. Diploma in Regulatory Affair
Global Institute of regulatory affairs, Pune
2012,

P.G. Diploma in Clinical Research and Clinical Data Management
IOCB Bangalore 2011,

M.Sc. Biotechnology
Punjabi University Patiala, Punjab *2008*,

PERSONAL ATTRIBUTES

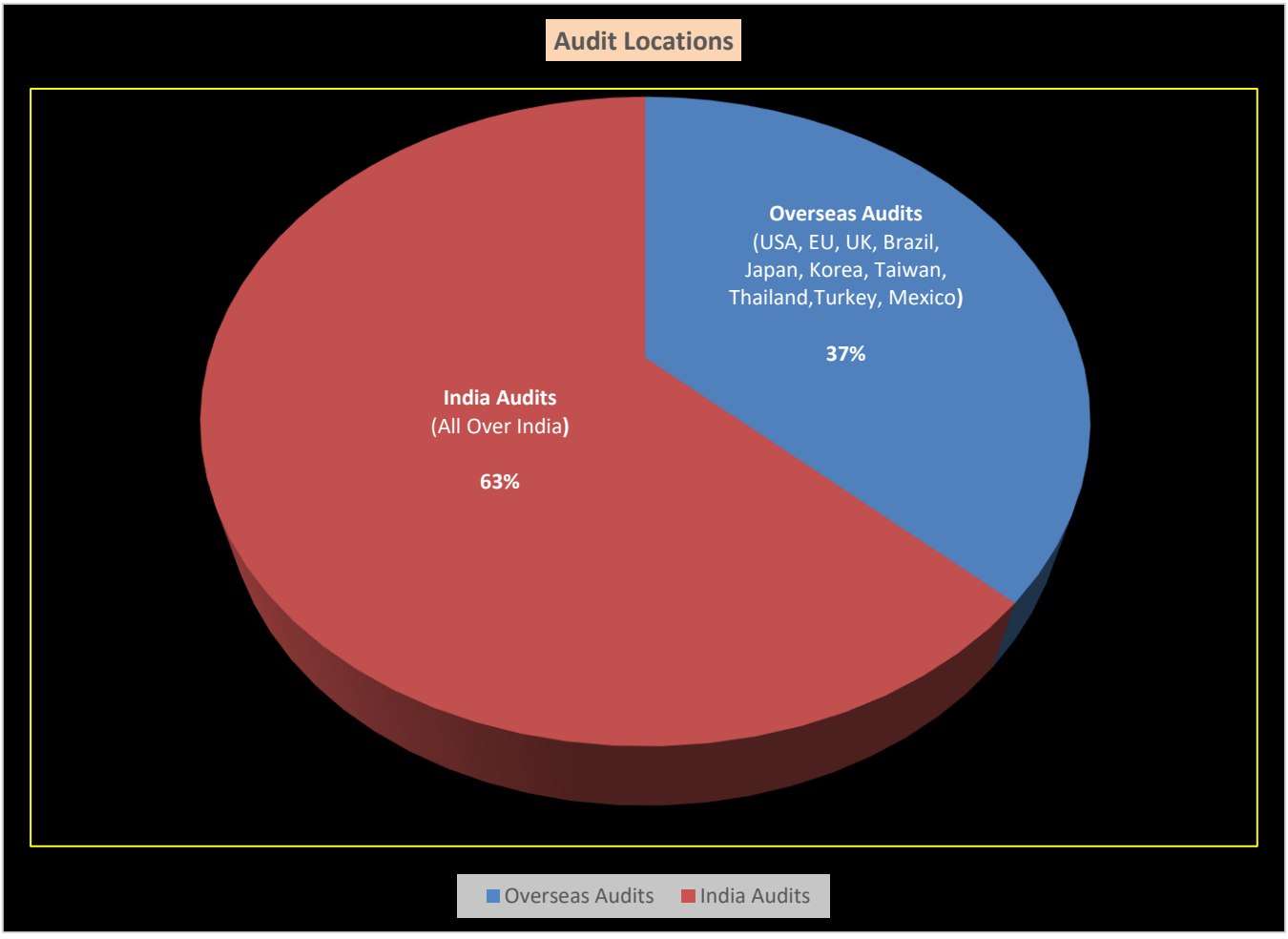
Impeccable Analytical skills | Unwavering Professionalism | Intellectual Curiosity | Innate Problem-solver

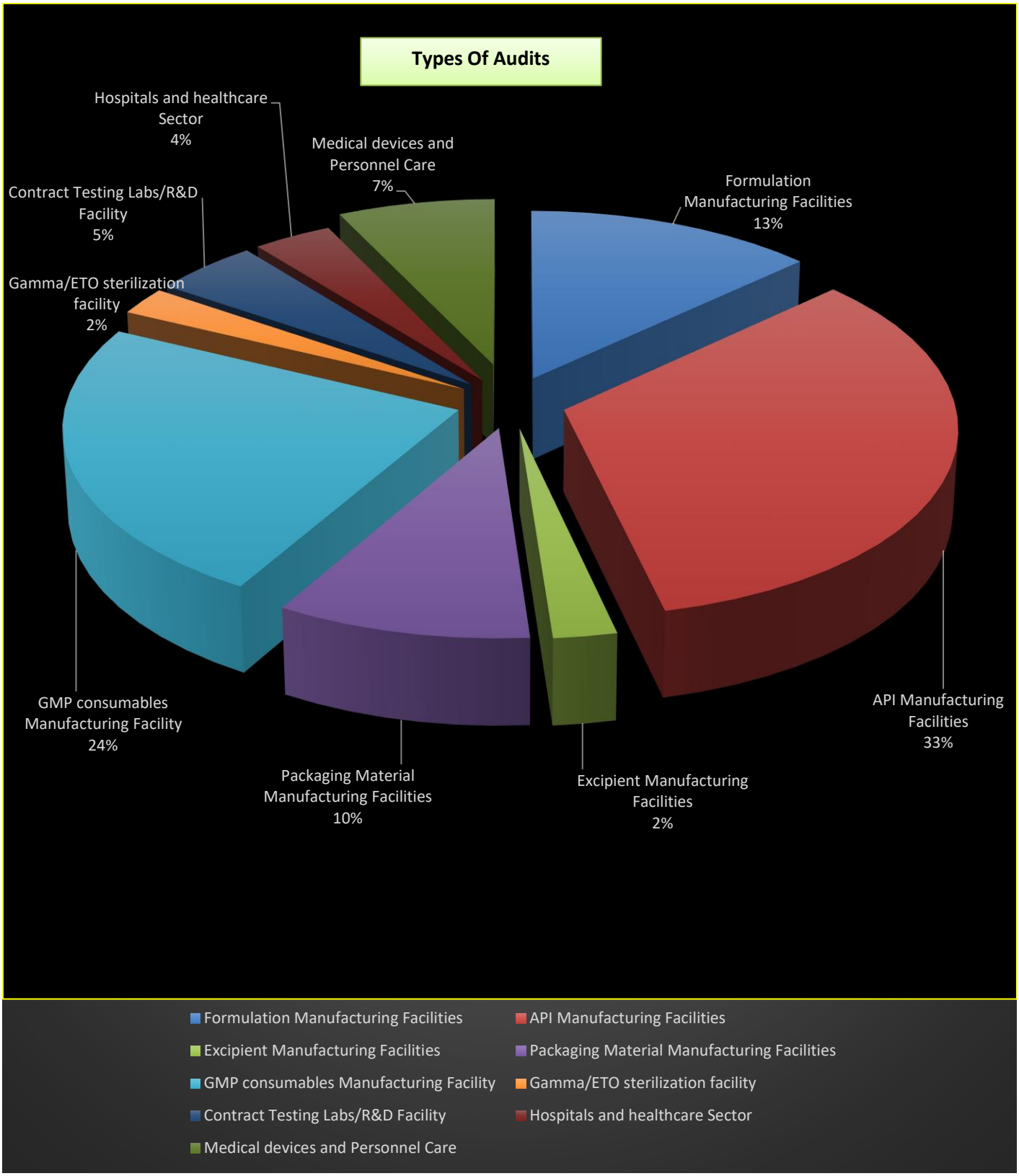
LANGUAGES

English ◉ ◉ ◉ ◉ ◉ Hindi ◉ ◉ ◉ ◉ ◉

GxP AUDIT EXPERIENCE

Sr. No.	Type of Facility	No. of Audits
1.	Formulation Manufacturing Facilities	**11**
2.	API Manufacturing Facilities	**28**
3.	Excipient Manufacturing Facilities	**02**
4.	Packaging Material Manufacturing Facilities	**08**
5.	GMP consumables Manufacturing Facility	**20**
6.	Gamma/ETO sterilization facility	**02**
7.	Contract Testing Labs/R&D Facility	**04**
8.	Hospitals and healthcare Sector	**03**
9.	Medical devices and Personnel Care	**07**




Types Of Audits
Hospitals and healthcare Sector 4%
Medical devices and Personnel Care 7%
Formulation Manufacturing Facilities 13%
Contract Testing Labs/R&D Facility 5%
Gamma/ETO sterilization facility 2%
GMP consumables Manufacturing Facility 24%
Packaging Material Manufacturing Facilities 10%
Excipient Manufacturing Facilities 2%
API Manufacturing Facilities 33%
Formulation Manufacturing Facilities
API Manufacturing Facilities
Excipient Manufacturing Facilities
Packaging Material Manufacturing Facilities
GMP consumables Manufacturing Facility
Gamma/ETO sterilization facility
Contract Testing Labs/R&D Facility
Hospitals and healthcare Sector
Medical devices and Personnel Care