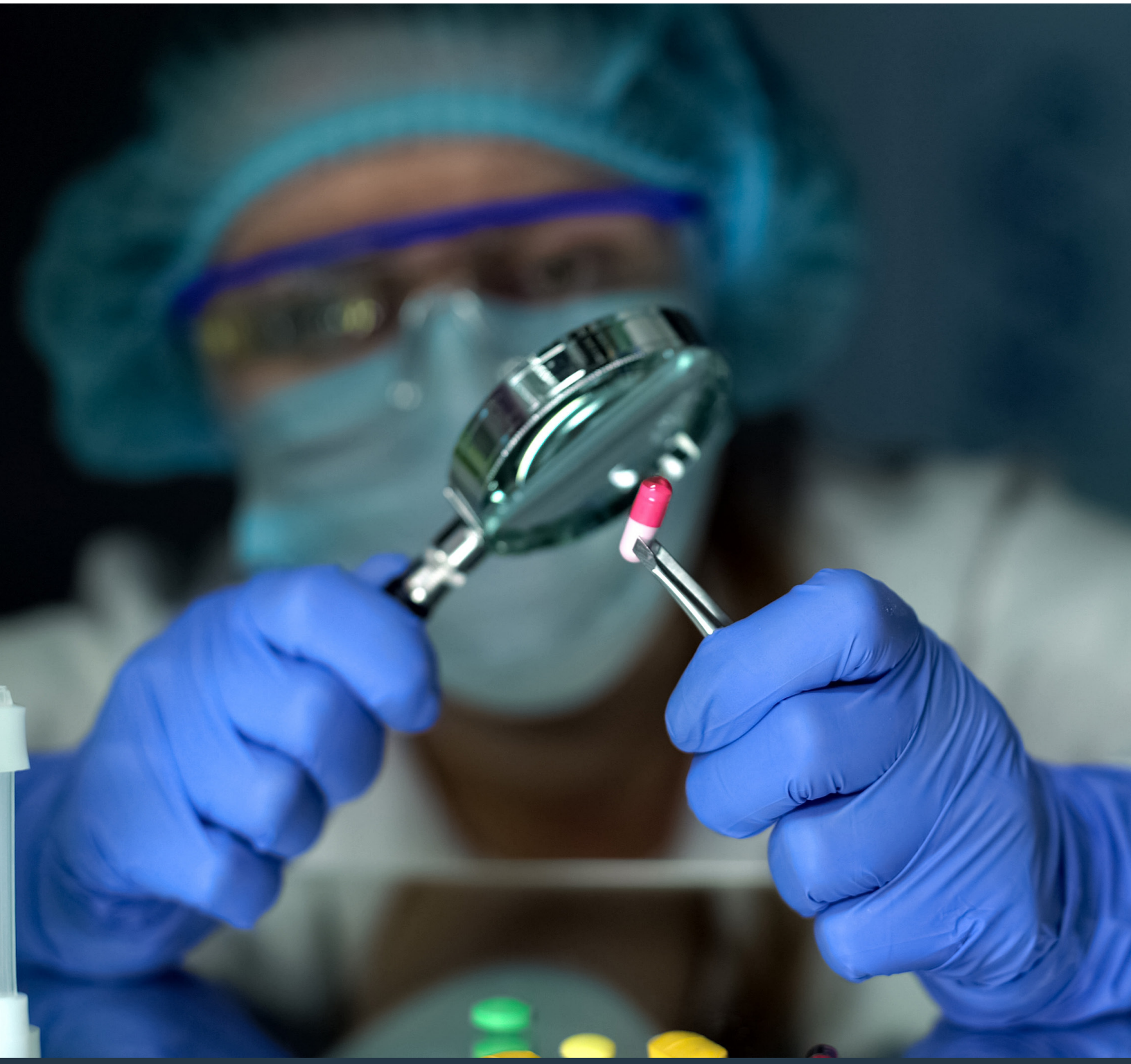
Piramal
Pharma Solutions



WHY QUALITY IS CRITICAL TO PATIENT CENTRICITY

High-quality manufacturing is the bedrock of the pharmaceutical industry. Contract service providers need to consistently adhere to quality standards to ensure the safety of patients and fulfill customer orders on time and on full, first time, every time.

While pharmaceutical quality is often discussed in the context of regulatory requirements and compliance to regulatory requirements, pharmaceutical manufacturers with a culture of quality have a broader, more positive perspective on ensuring compliance. Such companies establish and implement robust quality processes because they believe it ensures quality culture, patient centricity, data integrity and scalable compliance. It's also the right thing to do for their customers and, in particular, the patients who use the medicines they make.

In this patient- and customer-centric view of quality, unwavering compliance is about more than just meeting the demands of global regulatory agencies; it is a vital part of a company-wide commitment to the operational excellence and consistent on time, in full order delivery that is needed to ensure customers can provide patients with the life-changing medicines they need, when they need them.

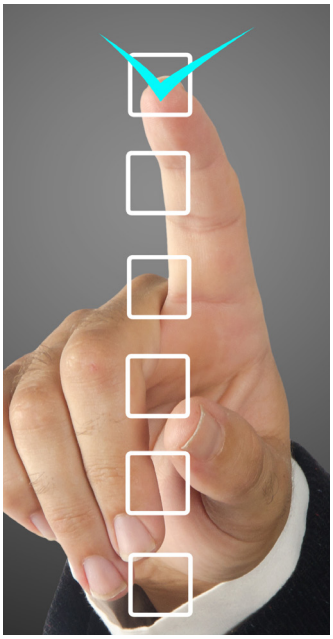
How Piramal Ensures Quality

At Piramal Pharma Solutions (PPS), a contract development and manufacturing organization (CDMO), a deeply ingrained focus on patient and customer-centricity has manifested in a multi-faceted, three tier quality model that involves all of its 10 global sites and employees up to and including the CEO. These tiers are closely integrated to ensure execution robustness. Predefined quality strategy with regular reviews enables continuous improvement and close alignment to business and regulatory changes. Quality processes are guided by a high level policy document that ensures quality culture, patient centricity, data integrity and scalable compliance. PPS's exemplary quality track record is in synchrony with company's purpose of "Doing Well and Doing Good."

PPS' quality model connects every part of its business. Actions and strategies formed at a global level, such as regulatory interpretation and best practice training, feed into the quality initiatives at central cells across regional and site levels. At a regional level, PPS considers factors affecting all facilities across the globe, such as cultural challenges and empowering sites to focus on more local requirements including technology, people, and product profiles. PPS has a robust escalation and governance mechanism that helps us identify issues at right time and helps resolve them with adequate leadership support.

Activities at each level form part of a quality governance process. Quality tools are a vital part of this process. These tools take raw data provided from sites and process it to generate insights that inform the actions of the vigilance group and ultimately ensure that PPS continues to make products that meet the needs of its customers and patients.

Predict

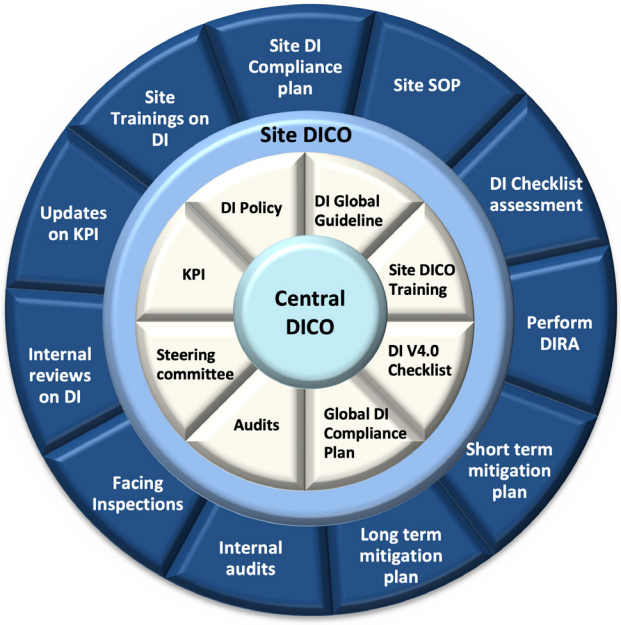


The portfolio of quality tools includes SENSOR, which PPS uses to measure the overall quality health of its sites. SENSOR turns raw data from a facility on parameters such as data integrity compliance, deviations, change controls, complaints and more into an overall score that shows if the site is living up to PPS' rigorous quality expectations. The Site Leadership Team receives SENSOR scores once every 4 months, enabling leaders at the company and facility level to see how sites are performing and track changes over time.

SENSOR is complemented by Predict, a tool for determining the likely outcome of an inspection of a site. Predict considers inputs including the Six system checklist, SME readiness and data integrity compliance to assess and predict audit outcomes. The checklist yields a score that indicates if a site is a risk to compliance, product quality, or, in the worst case scenario, patients. By combining the score with other pieces of evidence, PPS ensures every site is always inspection ready and thereby cuts the risk that noncompliance and failure will prevent it from meeting its commitments to customers and patients.

Maintaining Data Integrity

PPS' portfolio of quality tools also includes Calculus, which determines the compliance of its sites against data integrity requirements. Data integrity compliance is critical because it assures the regulators and customers that the end products meet all required quality standards. Recognizing that, PPS' quality team ticks off a data integrity checklist and conducts site gap assessments, the results from which are combined with information on automation to give a data integrity score for each facility.



Calculus thereby enables PPS to evaluate if its robust data integrity framework is working. The data integrity model facilitates the flow of information between central and site-level data integrity teams to support the rollout of policies, guidelines, and white papers, the development of compliance plans for each facility, and the advocating of transparency and failure reporting on the shop floor. A transparent approach in which shop floor employees report any new issues to the site team helps in enhancing data integrity controls and effective improvement, which in turn helps enact changes to ensure the problems are eliminated from the production line.

PPS' corporate team checks the effectiveness of the data integrity actions by auditing sites. The audit program, which also assesses compliance with good manufacturing practices, evaluates sites at least once every financial year. Along with announced audits on mutually agreed dates, the corporate team can conduct surprise assessments as well. Sites have no prior warning of these inspections or knowledge of the agenda.

The surprise inspections are part of the broader effort to ensure sites are always audit ready, which includes the aforementioned Predict tool and initiatives including the Quality Academy. Through the academy, PPS provides bespoke training intended to increase the ability of people to achieve quality goals such as permanent audit readiness and sustained compliance.

Driving Continuous Improvement

PPS' commitment to training is, in part, a reflection of the ever-changing nature of the environment in which its sites operate. Practices that facilitated the consistent supply of high-quality medicines to customers and patients in the past may be rendered outdated by changes to regulations and other aspects of the operating environment.

To mitigate that risk, PPS is continuously evaluating changes in the operating environment through its work on process-driven continuous improvement and risk management cycles. PPS feeds multiple sources of key information including customer feedback into a continuous improvement program. The cycle drives outcomes such as infrastructure upgrades and specification changes to ensure PPS is continuously adapting to new information and the evolution of the business environment.

The QUENCH quality intelligence platform exemplifies PPS' focus on ensuring its teams have all the information they need to consistently execute their patient and customer-centric strategies. QUENCH is a repository for regulatory guidelines and rules. The central team identifies new and updated regulatory documents and sends them to quality heads at PPS. QUENCH also circulates warning letters, enabling sites to evaluate their own compliance against real-world observations made by regulatory agencies about other facilities

Ensuring Quality Across a CDMO

CDMOs need to consistently adhere to manufacturing standards that meet or exceed expectations to be patient and customer-centric organizations. However, manufacturing is far from the only part of a CDMO that needs to be committed to quality. At PPS, regulatory services and pharmacovigilance are also key areas of quality focus.

The regulatory services team has a "Right First Time" ethos that echoes PPS' broader commitment to delivering projects on time and in full. By getting regulatory submissions right the first time, the team strives to avoid problems that force patients to wait longer for life-changing medicines.

"Right First Time" is more than just a slogan for PPS; the concept shapes its approach to regulatory services. Guided by the principle, PPS has built a regulatory services team with extensive experience in filing regulatory submissions and obtaining approvals from regulatory agencies across the globe. In addition to Regulatory Affairs, the team members have an average of around 20 years' experience in the pharmaceutical industry, which also include hands-on proficiency in allied departments like R&D (Formulation and Analytical Development), Quality Control (QC), and Production. Reflecting PPS' customer-centricity, the regulatory services team takes an open, transparent, proactive, and process-driven approach to submissions.

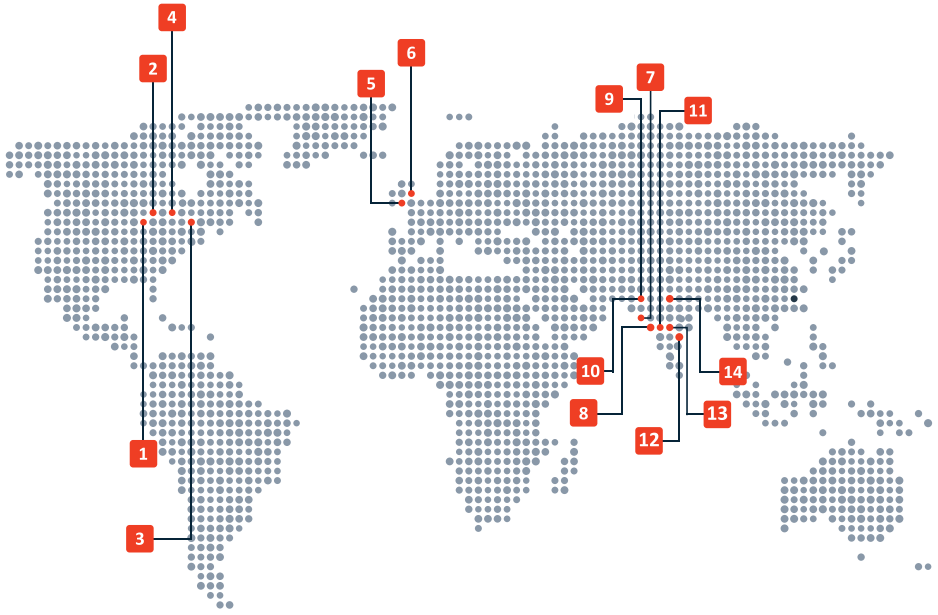
PPS' global submission capabilities sit alongside its expertise in labeling and artwork, e-Publishing, and chemistry, manufacturing, and controls consulting in a one-stop shop for regulatory services. The breadth and depth of capabilities have enabled PPS to help innovators and generic companies with filings covering a range of dosage forms in regulated and semi-regulated markets.

Once a product comes to market, PPS continues to ensure patient safety through a focus on quality at its pharmacovigilance services unit. The unit works with quality management systems, Oracle Argus safety databases, and end-to-end case processing and submissions to gather, process, and act on reports of adverse events. PPS has staffed the integrated signal-risk management and medical writing teams with experienced professionals, resulting in a unit of trained drug safety personnel, including medically qualified physicians, that has more than 100 years of aggregate experience.

While the activities undertaken by PPS' manufacturing, regulatory services, and pharmacovigilance services units are very different, they share the common goal of serving patients and customers. By identifying and mitigating risks to the consistent supply of safe, high-quality medicines, PPS' quality experts across the three units do more than just enable compliance with all governing standards; they ensure customers and patients receive the products they need on time, every time.

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), where everything we do, we do for the patient. The company specializes in integrated services and end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe, and Asia. This enables us to offer a comprehensive range of services including drug discovery solutions, process and pharmaceutical development services, clinical trial supplies, and commercial supply of APIs and finished dosage forms. We also offer specialized services like the development and manufacture of highly potent APIs, antibody drug conjugations, and manufacturing of hormonal drugs. Our capability as an integrated service provider and experience with various technologies enables us to serve innovator and generic companies worldwide. Our development centers and manufacturing sites have accreditations from regulatory bodies in the U.S., Europe, and Japan. With a pool of 700+ scientists including 150 Ph.D.s across the globe, we are committed to research and development programs. To know more visit: www.piramalpharmasolutions.com | Social Media: Twitter, LinkedIn

OUR GLOBAL PRESENCE



1 LEXINGTON, USA
Sterile Development & Manufacturing
USFDA, PMDA

2 RIVERVIEW, USA
HPAPI Development & Manufacturing
USFDA, PMDA

3 SELLERSVILLE, USA
Formulation Development & Manufacturing
USFDA, EMA

4 AURORA, CANADA
API Development & Manufacturing
USFDA, PMDA

5 MORPETH, UK
API & Formulation Development & Manufacturing
USFDA, MHRA

6 GRANGEMOUTH, UK
ADC Development & Manufacturing
USFDA, MHRA

7 RABALE, INDIA
API Development

8 TURBHE, INDIA
Peptide API Development & Manufacturing
USFDA

9 AHMEDABAD - PDS, INDIA
Drug Discovery

10 AHMEDABAD - PPDS, INDIA
Formulation Development
EU Finland

11 MAHAD*, INDIA
Vitamins & Minerals Premixes
USFDA, WHO-GMP

12 ENNORE, INDIA
API Development & Manufacturing
WHO-GMP

13 DIGWAL, INDIA
API Development & Manufacturing
USFDA, MHRA

14 PITHAMPUR, INDIA
Formulation Manufacturing
USFDA, EU Finland

SHANGHAI, CHINA
• Sourcing Office

Note: *Dietary Ingredient

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