FDA/CDER SBIA CHRONICLES
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FDA's Office of Pharmaceutical Quality: ONE YEAR IN

One Quality Voice is the motto of the FDA Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality (OPQ). Launched in January 2015, OPQ's mission is to address gaps in drug quality and ensure that quality medicines are available for the American public, with a vision of being a global benchmark for the regulation of pharmaceutical quality. The new Office combines non-enforcement-related drug quality work into one streamlined super-office making OPQ more accessible to the manufacturers of drug products.

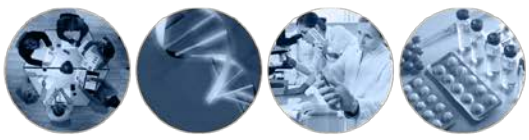
FDA established OPQ to improve the internal assessment of drug quality and to facilitate interactions with industry. OPQ strives to improve drug product quality by encouraging the modernization of manufacturing technologies and using proactive, collaborative approaches to identify and mitigate quality issues before they lead to drug shortages or recalls.

Why are OPQ's goals and accomplishments important to industry? OPQ will ultimately:

- Enhance quality drug assessment by integrating quality review and inspection
- Establish consistent quality standards and clear expectations for industry
- Anticipate quality problems before they develop and help prevent drug shortages
- Use quantitative metrics to help monitor quality

Drug Approvals: In its inaugural year, OPQ worked closely with other CDER Offices on facility inspections and the review of applications, and had major contributions in achieving CDER's drug approvals for 2015. OPQ played a critical role in the approval of applications for CDER's first biosimilar, first 3D printed drug product, first continuous manufacturing, and first generic glatiramer acetate products.

OPQ met or exceeded Prescription Drug User Fee Act (PDUFA), Biosimilar User Fee Act (BsUFA), and Generic Drug User Fee Amendments (GDUFA) goals. On the new drug application (NDA) and biologics license application (BLA) side, OPQ meets the criteria and timelines set forth in the 21st Century Desk Reference Guide the large majority of time. On the abbreviated new drug application (ANDA) side, and for cohort years 3, 4, and 5, OPQ provides the quality recommendation to the Office of Generic Drugs 30 days prior to GDUFA date. As of January 2016, OPQ also reduced the generic backlog of pre-FY 2015 ANDAs by more than 40% with actions pending OPQ from 2500 to 1471.



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Integration of Review and Inspection: One of OPQ's value statements is to have one quality voice by integrating review and inspection. To provide seamless integration of review, inspection, surveillance, policy, and research across the product life cycle, OPQ constructed review tools, work aids, and flow diagrams for BLA, NDA, and ANDA assessment. For instance, reviewers are kept informed of inspectional findings, and field investigators are informed of review issues. This type of collaboration is termed 'Team-based Integrated Quality Assessment (IQA),' and is ongoing for all original BLAs, NDAs, and ANDAs. Approximately six BLAs, one NDA and 40 ANDAs have been approved so far employing the IQA approach and many more applications are still in review.

Drug Quality Standards: One quality voice is also maintained by establishing scientifically sound quality standards and applying risk-based approaches, ultimately improving FDA's oversight of quality throughout the lifecycle of a drug product. In 2015, OPQ published many documents to help industry in maintaining drug quality. A few highlights include:

- a draft guidance on Dissolution Testing and Specification Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutics Classification System Class 1 and 3 Drugs
- a draft guidance on Botanical Drug Development
- a draft guidance on Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products

OPQ also continued to work with international regulators on ICH Q12. Additional guidance documents are located on our webpage.

Product Quality Oversight: To transform product quality oversight from a qualitative to a quantitative and expertise-based assessment, OPQ developed a plan for facilities inventory. To implement the facility inventory plan, OPQ evaluates site and or product data from multiple data sources to determine which sites are "real" (i.e., we know where they are and what products they make). In the process of reconciling data among different data sources, OPQ works with the data owners to fix discrepancies and refers sites that fail to register or list their drug products to CDER Office of Compliance for appropriate regulatory and enforcement actions. This plan is currently being implemented.

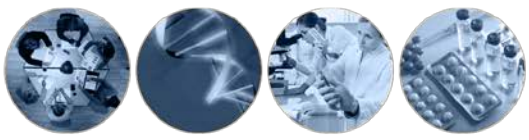
OPQ also published a draft guidance on quality metrics. To implement the Quality Metrics Guidance, OPQ is establishing a statistical signal detection program that will assess estimates of site and product level performance. Using statistical tools, FDA can monitor the quality of sites and products over time and compare them against other sites and products.

Development of Emerging Pharmaceutical Technology: Emerging pharmaceutical technology is important to enhance pharmaceutical quality and potentially reinvigorate the pharmaceutical manufacturing sector in the United States. In the past year, OPQ has shown its interest in encouraging the development and adoption of emerging pharmaceutical technology by forming an Emerging Technology Team (ETT). The ETT has successfully engaged with a number of pharmaceutical companies on innovative manufacturing technologies, including continuous manufacturing processes, and provided constructive feedback to them. OPQ also published the Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base guidance document.

Clearly, OPQ has accomplished a great deal in its first year. With OPQ's formation, CDER is better able to align all drug quality functions, including review, inspection, and research. OPQ is at the center of supporting CDER's mission of ensuring that safe, effective - and *high quality* - drugs are available for the American public.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

Issues of this newsletter are archived at http://www.fda.gov/cdersmallbusinesschronicles



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