

## APQR: A Mandatory Ritual or Constructive Review Process?

APQR is a concept that presents an organization's commitment to quality in all its manufacturing operations. It needs to be understood in terms of the value it is going to deliver to the industry

“Pharmaceuticals and life sciences industries have been complying with so many regulatory guidelines that at some point, tasks become mechanical. There is a lack of motivation and intent. In such scenarios, even if the guidelines are met precisely, are we justifying the big picture – safeguarding human well-being?”

APQR (Annual Product Quality Review), a resonating term in the pharmaceutical industry originated in the '70s. First proposed on February 13, 1976[1], APQR initially faced objections across the industry as companies refrained from preparing written summaries for each product. FDA, after considering the views of numerous industry experts published the requirement as final current good manufacturing practices (cGMP) regulations for drug products under 21 CFR 211.180(e).

APQRs assess the quality standard of drugs and the consistency of manufacturing processes while also ensuring the appropriateness of prescribed specifications and establishing control procedures. According to FDA, the preparation of these review reports must be an annual affair so that drug manufacturers identify the trends and need for any changes required during the manufacturing process.

### Is Compiling an APQR Enough?

As everyday tasks often become routine, they lose their essence. The same is true for the APQR process too. As it is an annual requirement, every company that comes under scrutiny deploys a team specialized in the process. This sometimes involves assigning team members from crucial departments. Transitioning tasks demand a change of focus and time to adapt to the process.

Once things are settled, the team begins the actual job of

preparing the annual product quality report. Since this is an annual process, it has a predefined set of tasks levelled down to get the desired review report in a prescribed format. However, is only pushing the data into a format enough to derive value out of the report? Obviously, the answer is NO.

APQR is a concept that presents an organization's commitment to quality in all its manufacturing operations. It needs to be understood in terms of the value it is going to deliver to the industry. Mechanically pulling out data and feeding it into the formats is a trivial thing to do.

### Automating APQRs is Just the First Step

Nowadays life sciences and pharma organizations have generously accepted the digitalization trend. Realizing its benefits and vitality in today's competitive era, companies have begun to automate their APQR processes. However, the ques-

tion remains – Is Compiling an APQR enough?

Although APQR software automates the entire process, which really saves time and maintains accuracy throughout, it isn't contributing to the bigger picture. Let's try and understand the essence behind APQRs.

◆ **The core aspect:** If we think of APQR as a concept, it might have definitely arisen from a perspective – a perspective of creating a way to provide an uncompromised system that aims at keeping a check on the consistency of drug products manufactured.

### The Often-Overlooked Components

◆ **AGILITY:** Times and technology are changing fast. APQRs must possess the agility to quickly adapt to these changes.

◆ **FLEXIBILITY:** Every organization operates differently and has different organizational structures. APQRs must allow

for functional flexibility for user convenience.

◆ **ACCURACY:** Data is the foundation of an APQR, and it undeniably should be accurate. The system must empower organizations with correct data to ensure integrity in reports.

◆ **ACCESSIBILITY:** Today everything needs to be instant. However, APQR is usually an annual affair. This still has a possibility of compromising on the consistency of processes. As the review is annual, year-long manufacturing and the products can suffer a delayed notice of deviations or inconsistencies. The APQR must also be instantly available for a quick glance.

◆ **ACCOUNTABILITY:** A process holds worth only when it is accountable for its performance. APQR is a critical process and must be entirely accountable for all the efforts and time

that go into its preparation.

### APQR Revolution = Automated + Anytime

If you are still wondering whether there is an APQR that fulfills all of the missing elements, the answer is affirmative! CaliberAPQR is a revolutionary product and the first of its kind in the industry. Defying all the odds and setting new horizons for the regulated industry, CaliberAPQR brings immense possibilities to add value to the mandatory ritual of preparing APQRs. It rightly transforms the way these review reports have been generated until now. The APQR system promotes agility, flexibility, accuracy, accessibility, and accountability.

### CaliberAPQR –

- ◆ Reduces months' efforts to a single click
- ◆ Enhances traceability
- ◆ Displays trends instantly
- ◆ Analyses data aptly
- ◆ Provides statistical calculations
- ◆ Promotes ANYTIME feature
- ◆ Includes attachments for ready reference

### Why Quality Must Never Be Routine?

“Quality Review Can Never Be Routine, It is a Culture That You Build.”

We need to think beyond marking all items in the dossier. In the life sciences and pharmaceuticals, quality has a distinct nature. It is a concept and has a focused perspective behind it. When an APQR meets convenience and usability, it is worth all the effort and adds more value to the entire process.

CaliberAPQR is a powerful entrant in this sector and is already taking the industry by storm. It is developed for value-driven, technically-sound enterprises of tomorrow. It is time we rethink our quality reports with a quality mindset. After all, APQR is meant to be a constructive review process!

