CASE STUDY

A Big Pharma Giant Partners with Global Pharma Tek (GPT) for Case Processing Resources & Services.

Prologue

Post marketing surveillance is an important process to monitor safety of the approved drug. The safety of a developmental drug must also be reported from clinical trials. When there is an adverse event (AE), then it required to be reported regardless of its validity. If it is a valid case justifying minimum criteria; Identifiable patient, Identifiable drug, Identifiable event and Identifiable reporter, then it should be reported to the regulatory authorities depends upon the nature of the event. The reports should be submitted within the timelines with good quality.

Circumstance

The world's top pharmaceutical company with headquarters in USA has been using services of various vendors to process cases and submiting to the regulatory. They wanted to move from existing database to the other database for case processing and looking for the resources to simplify their job. The timelines were stringent and the customer wanted to make this transition smoothly.

Resolution

For the past eight years, GPT has been in a long - standing global relationship with the customer providing premier resources delivering premium results in other projects. The GPT has pharmacovigilance resources & services in which, cases from solicited and unsolicited sources (spontaneous cases, literature cases and clinical trial cases) are processed and quality checked in customer's safety database. As a vendor, GPT has internal quality check systems, processes and procedures on which all the resources are given with in depth training. For the past eight years, GPT is been doing improving their efficiency in time & quality by anticipating good pharmacovigilance practices. Since 2011 GPT has been providing similar services to other customers immediately without any delay. We have developed internal QC process, validation process, and medical evaluation process. The in-house scientific and medical expertise have been helpful building valuable resources in GPT. The resources of the GPT must be rigorously trained, simulated and read and sign data protection agreements. As a best practice, GPT keeps training records of all their resources. All the resources were certified through case processing to ensure timely submissions and quality.

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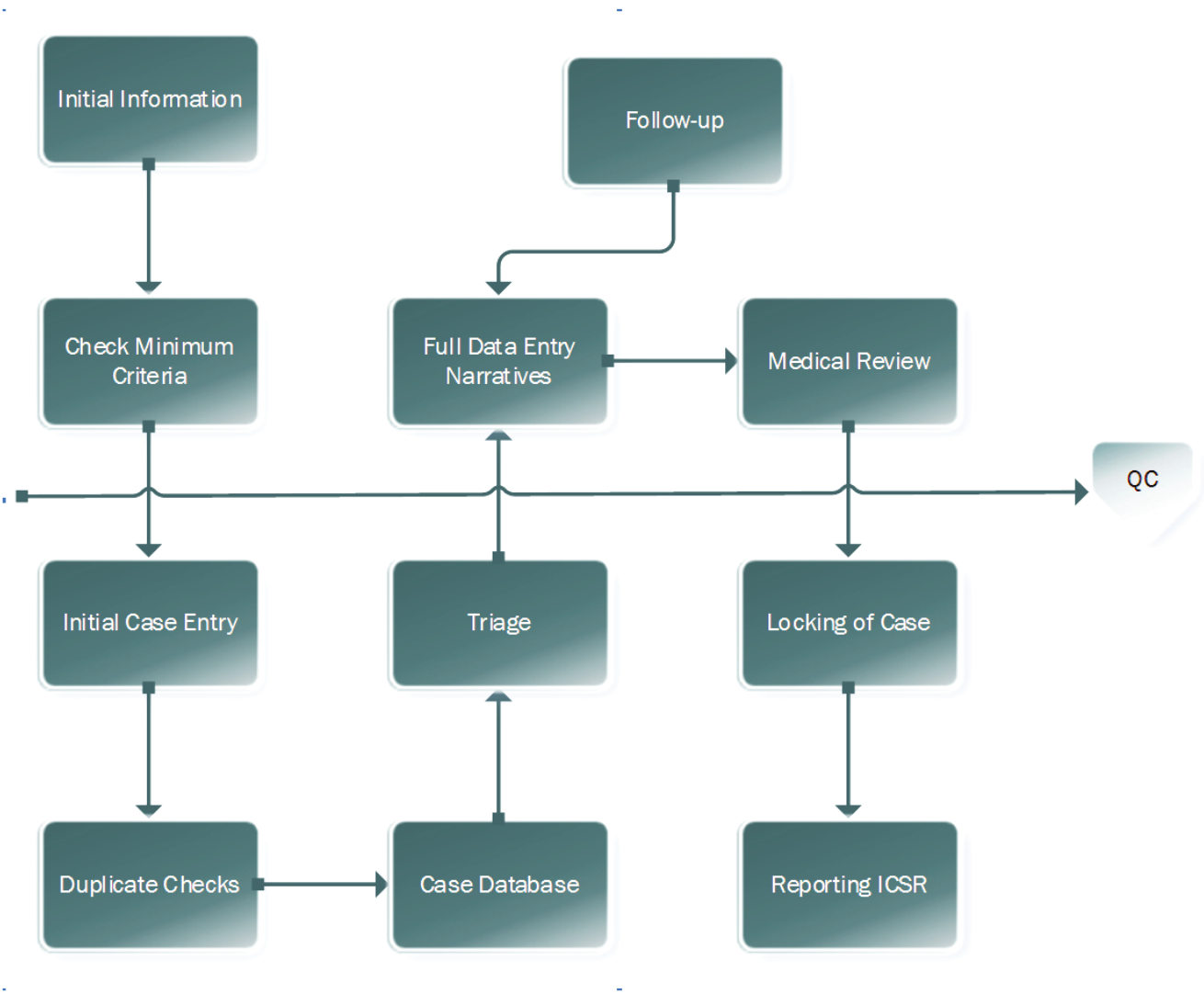
Our resources serving:



There is a liaison between GPT and the customer facilitating effective communications. The parameters for service level agreement penalty were based on service availability and service quality. Any quality issue or non-compliance will bring penalty over GPT.

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Result

The implementation of resources at the client location was successful with high performance by associates. The customer gained confidence and GPT built the trust and the relationship been continuing for the past eight years. Our associates never missed the timeline and quality metrics. The quality targets have been exceeded project by project but GPT associates have achieved quality of 99-100%, higher than the key performance indicators set by the customer within the company (95%). The teams have been delivering above and beyond, demonstrating their flexibility to meet the customer's expectations.

In eight years, our teams have processed more than 10000 cases (serious and non-serious) and delivered all cases within the timeline. With GPT's practices and processes the customer had saved their valuable time and money. The shortened process and unique quality checks enhanced the quality and submission timelines.

Quality was checked in each and every step

- Self-check-list for associate
- Stage-wise QC
- Final QC on randomly selected ICSRs

Other Specialties

- Literature review & databasing
- Clinical trial cases

Summing up

Submission of Individual case summary reports (ICSRs) to the regulatory bodies is vital during post-marketing drugsafety surveillance and the fate of any drug depends upon the quality submissions. Matured processes and innovative quality systems will ease the process. Continuous learning, in-house quality systems, tremendous training, timely updating resources and systems, and compliance are the core values of GPT

"Partnered with top pharma giants and providing seamless support in Pharmacovigilance & Drug Safety"