Research, development, production and safety control activities for supplying superior pharmaceuticals of outstanding quality for people with confidence

Quality Assurance System

Fundamental Policy
As a pharmaceutical company, Takeda has a firm commitment to two principles. The first is adhering to the corporate philosophy of Takeda-ism by acting with integrity at all times. The second is building a base for global operations guided by the corporate mission statement, “striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products.” These principles mean that the highest priority is given to safety of patients and customers who use Takeda products. By providing products of outstanding quality accompanied by proper information we are fulfilling the mission of meeting expectations and earning the trust of various stakeholders we serve. One key element to achieve Takeda’s mission is strict compliance with applicable laws and regulations. Equally important is a comprehensive quality assurance and safety control system to align different activities in research, development, production and safety control. Takeda has structured this system above all to supply safe, high-quality products that patients and customers can use with complete confidence. Takeda does its best to maintain the reliability of all its operations at all stages extending from research, clinical studies, manufacturing, distribution, and providing information on appropriate use, to monitoring and analysis of safety and quality information as the products become widely used.

Quality Assurance Spanning the Entire Product Life Cycle

Research and Non-Clinical Studies
Takeda stringently manages studies and maintains data integrity and also strictly follows each country’s regulation of GLP (Good Laboratory Practice) for non-clinical studies to assess the safety of candidate compounds of pharmaceutical products.

Clinical Development
All of Takeda’s clinical studies which are conducted anywhere in the world comply with the Japanese, European and U.S. International Conference on Harmonization-Good Clinical Practice (ICH-GCP), in addition to national and regional regulations as well as the Takeda Group’s own standard operating procedures along with adherence to the protocol.

Manufacture of Pharmaceutical Products
Takeda complies with GMP (Good Manufacturing Practice), a set of regulations for the manufacturers and quality control of pharmaceuticals, and keeps up to date with the latest revisions to these regulations. We also apply our own quality standards to assure that Takeda pharmaceutical products meet international requirements for quality regardless of where they are manufactured.

Post-Marketing Quality Control, Safety Surveillance and Promotion of Appropriate Use of Takeda Pharmaceutical Products
Even after a drug is brought into market, Takeda has an extensive program for collecting information from patients

Product Life Cycle and Regulations

Regulations for Pharmaceutical Products

<table>
<thead>
<tr>
<th>Regulations based on the Pharmaceutical Affairs Law</th>
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<tr>
<td>GLP: Good Laboratory Practice Standards for conducting non-clinical studies relating to pharmaceutical product safety</td>
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<td>GCP: Good Clinical Practice Standards for conducting clinical studies</td>
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<td>GMP: Good Manufacturing Practice Standards for manufacturing and quality control for pharmaceutical products</td>
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<td>GQP: Good Quality Practice Quality control standards for pharmaceutical products</td>
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<td>PV: Pharmacovigilance Standards for monitoring the safety of pharmaceutical products</td>
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<td>GDP: Good Distribution Practice Standards for distribution of pharmaceutical products</td>
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<td>GVP: Good Vigilance Practice Safety control standards for pharmaceutical products after manufacture and sale</td>
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and customers around the world about the product’s quality and safety. Examining and evaluating obtained information allows us to detect potential quality and safety issues at an early point and make continuous improvements in the quality and carry out safety control. We also provide information on the appropriate use of our products. In Japan, we follow the GQP (Good Quality Practice) regulations for quality control of pharmaceutical products and GVP (Good Vigilance Practice) regulations for safety control of pharmaceutical products.

The Takeda Quality Assurance System

Takeda has established a global policy for quality assurance. All Takeda group companies around the world are required to perform their quality assurance activities in line with this policy. The policy is intended to maintain a strong awareness of the importance of quality assurance related activities among management and employees at each company. Another objective of the policy is to clarify roles and responsibilities for quality assurance of each division of the companies.

The Global Quality Assurance Department is the nucleus of Takeda group’s quality assurance activities. Creating the global policy as well as the guidelines for implementing the policy is the main responsibility of the department. The department is also responsible for raising awareness of the policy and promoting the establishment of a quality assurance system at each Takeda company as expected for a global enterprise. At group companies worldwide, quality assurance departments conduct quality oversight and audits and provide guidance on activities throughout the entire product life cycle, extending from R&D to manufacturing, distribution and delivering of products with appropriate information to patients and consumers. When an audit reveals a problem, the operation department concerned is required to submit progress reports so that they may receive follow ups on corrective measures.

Furthermore, the quality assurance departments of group companies maintain good communication centered on the Global Quality Assurance Department. This allows sharing information about quality issues and effective solutions.

Takeda’s quality and safety control programs in Japan have been realigned following the April 2005 enactment of amendments to the Pharmaceutical Affairs Law. Managers responsible for quality assurance and safety control have been appointed respectively and assigned under the supervision of the statutory Supervisor General (Quality and Vigilance) who is the general manager of the Global Quality Assurance Department. These three executives coordinate closely to establish a system to ensure strict compliance with GQP and GVP with regard to Takeda’s ethical drugs and consumer healthcare drugs.

Quality Assurance System Global Network

For further details about Takeda’s quality assurance system, please see the CSR Data Book (PDF)
http://www.takeda.com/csr/