<Keynote Lecture>

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PMDA's review period took the longest time in the past but has become the fastest reviewing authority in the last decade. The reason for achieving this change is that in addition to increasing the number of staff members, there have been efforts such as science regulations established internally. Specifically, an overall approach has been undertaken with a priority focus on (1) Philosophy, (2) Regulatory science, and (3) International partnerships. With regard to the "philosophy", we made all staff contribute to delivering more effective and safer medicines to medical institutions more quickly, with the top priority on improving public health and safety. Synergistic results have been obtained by matching the direction of all staff. Also, in February last year, we devised guidelines to promote regulatory science and to aim for rational medical care. Regarding "Regulatory Science", in order to improve this we established the Regulatory Science Center in April this year. In order to further raise the science level, we have established a scientific committee for collaboration with academia and have a comprehensive partnership agreement. Innovation is indispensable not only for pharmaceutical products but also for the regulatory science of regulatory agencies, and PMDA will promote this. As a new initiative, we are challenging the pharmaceutical affairs strategy consultation project, pioneer designation system, conditional early approval system, and MID-NET project etc. Regarding "international partnerships", we are trying to solve common issues in cooperation with various regulatory authorities. There are many international collaboration groups, and, for example, an organization called ICMRA has been established in which the ministerial class of each regulatory authority receives overviews of technical level cooperation, and this is the core of the group which contributes to strengthening international partnerships. In addition, in April 2016, the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) was established as a place to share the knowledge and experience of PMDA with the staff of regulatory authorities in other countries. We held 16 training seminars so far, and plan seminars that will help us practice over 9 times this fiscal year. PMDA hopes to continue to provide reasonable medical care to patients worldwide, but PMDA alone cannot achieve this. We would like to work hard together with all of you to improve public health for patients.