

The construction of the Quality Assurance Center, which carries out the key quality assurance activities of the Amano Enzyme Group, was completed in August 2008 within the site of the Nagoya Plant (located in Kita-nagoya City).

The quality assurance center was built in accordance with the concept of "a vibrant and comfortable work environment" and the need for "centralized quality assurance and control throughout the Amano Enzyme Group." This center houses both the quality assurance and quality control departments. The Quality Assurance Department is responsible for assuring product quality, providing quality information for customers and addressing various regulations by anticipating the actions of the regulatory authorities in individual countries. We are also a member of the Japan Food Additives Association and various other organizations (the Enzyme Technical Association (ETA), the Association of Manufacturers and Formulations of Enzyme Products (AMFEP), the Japan Bulk Pharmaceutical Manufacturers Association, the Osaka Pharmaceutical Manufacturers Association, and the Japan Parenteral Drug Association) and have exerted our efforts to contribute actively to the development of the enzyme industry.

The Quality Control Department is responsible for evaluating product quality using standard, internationally approved testing methods in accordance with various official compendiums such as the Japanese Pharmacopoeia, the Japanese Standards of Food Additives, the Food Chemicals Codex, and the FDA/BAM (Bacteriological Analytical Manual).

Testing parameters used are as follows:

- Enzyme activities (starch saccharifying activity, starch dextrinizing activity, protein digestive activity, fat digestive activity, etc.)
- General tests (identification, loss on drying, etc.)
- Purity tests (heavy metals limit test, arsenic limit test, lead limit test, etc.)
- Microbial limit tests (total viable aerobic count, coliforms, *Escherichia coli*, etc.)

The Amano Enzyme Group assures our customers that we will continue to provide products, services and information, all of which are now controlled in the GMP-compliant laboratory in our Quality Assurance Center.

Description of the Quality Assurance Center
 Building: Steel construction, two floors above ground, total floor area approximately 1,900 m²
 Floor plan
 1st floor: Quality Assurance Department office, document storage room, meeting room, microorganism testing room
 2nd floor: Testing room, Quality Control Department office



Traditional Japanese foods such as sake (rice wine), miso (soy-bean paste) and shōyu (soy sauce), all of which are produced by Koji fermentation (the utilization of *Aspergillus oryzae*), are just some examples of the way in which enzymes have played a crucial role in the history of world-class biotechnology in Japan. Amano Enzyme Inc. is based on the tradition culture of Japan which can best be described as "living in harmony with nature and conserving natural resources" and has involved in the utilization of the enzymes generated by various microorganisms, such as *Aspergillus oryzae*, and plants and animals for many years.

Looking back on the history of the discovery and utilization of enzymes which seem to have originated in Japan, contributions are achieved by many universities and companies involved. Unfortunately, however, we have had no place to compile and publicize their accomplishments. In accordance with our corporate philosophy that "we create new value and contribute to society through the application of our enzymes," Amano Enzyme Inc. has therefore decided to collect materials including books related to the history of the discovery and utilization of enzymes and to set up a "Historical Archive of Enzymology" in order to make that information public.

In order to establish the enzyme library in 2010, a group comprised mainly of retirees from our company has already started collecting relevant data. We have also been informed that many universities and companies will supply invaluable books and data relating to enzymes. We are deeply indebted to many universities and companies for their continued support in setting up the Historical Archive of Enzymology.

We are now preparing to set up the Historical Archive of Enzymology, hoping that more and more people will gain a better understanding of enzymes and that we will thereby be able to contribute to the promotion and further utilization of enzymes.

We thank you for your assistance and co-operation in our project.

About the Historical Archive of Enzymology

1. Concept

To contribute to the public understanding of the history of the discovery and utilization of enzymes

2. Details

- 1) Exhibition of historical materials including books related to enzymes and the utilization of enzymes
- 2) Display of invaluable data and panels showing the historical development of enzymes and the utilization of enzymes
- 3) Setting up display corners to support and popularize the understanding of enzymes



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