

Iran Symposium – Series of lectures prove to be a complete success for the Engineers of AXI.TECH GmbH

Decision maker of the Iranian pharmaceutical industry as well as university scientists met on November 1st in 2006 to attend the „First Biopharmaceutical Customer Symposium Tehran“ together with arneg IR and the German AXI.TECH GmbH.

The cooperation between the Iranian company arneg IR and the German engineering company is already existing since 2006. The first contact has been established in that same year when AXI.TECH caught the attention of arneg IR, who were in search of a partner for GMP-compliant design for construction of cleanrooms. Result of the discussions is a perfect synergy between an Iranian building company and German engineering.

The cooperation was in equal an important part of the symposium, which was moderated by arnegs Research Advisor, Professor Abbas Taeb. N. H. Modarai, Managing-Director of arneg IR, appreciated the cooperation in his opening remarks and characterized the work with the German engineers as most positive.

The attendant president of the pharmaceutical industry association, Dr. Najafi, spoke of the pharmaceutical business situation and the interrelated restrictions. He pointed out that Iran will have to open up to keep up with international standards.

A Powerful Partnership – Dipl.-Eng. Bernd Geis, Managing Director of AXI.TECH GmbH, opened the scientific lectures with his speech about the cooperation with arneg IR in future and the West Asian market. Advantage of the cooperation is the combination of general contracting and project management, high-tech products and a reliable engineering service for the complete lifecycle of process plants and infrastructure facilities. These advantages make an impact on the customer in equal measure, who can rely on German engineering and project management which meets the GMP-standards at fair local prices and with an efficient communication. In order to further illustrate how the superordinate objectives in relation to customer orientation, excellent quality and realization to schedule and within budget of the project can be achieved through the cooperation, important elements should be outlined in the symposiums course.



Clean Systems Technology – An important aspect to achieve the objectives in relation to the customers orientation, excellent quality as well as in schedule and within budget, are innovations based on experience. This includes the clean media systems of AXI.TECH GmbH. Dipl.-Eng. Ruth Wohlfahrt had an overview of the technical systems in the pharmaceutical and biotechnology industry like clean media supply, HVAC-systems and clean room monitoring systems as well as of state-of-the-art regulatories and technical requirements. Ruth Wohlfahrt concluded with accenting the high importance of infrastructure facilities for the manufacturing of pharmaceutical dosage forms and stated that automated, PC-supported infrastructure systems will reduce a major part of the manual operation in future.



General Contracting and Project Management – Dipl.-Eng. Bernd Geis talked about the risks in investment projects of the pharmaceutical industry. At first he discussed the successful X-model of AXI.TECH GmbH for project management and quality assurance of GMP-projects. Advantage of this model is the cross linking of design and validation standards, critical checkpoints during the course of the project, the securing of GMP-requirements in spite of fast track organization as well as significant advantages concerning time and budget. The model brings together the elements of the Good Manufacturing Practice and the Good Engineering Practice. Bernd Geis gave a review about the project realization of AXI.TECH GmbH with its technical disciplines as well as about their project management from the start of the project to handover.



The importance of quality assurance within the project handling accented Dipl.-Eng. Karin Stoller. In her lecture she talked about the standards of quality assurance which shall be adapted project-specific. Monthly reviews, beginning with project start and –planning, ensure at AXI.TECH an early fault detection so a successful project close out with a following knowledge management is secured. The quality assurance in process engineering is based on preventive trainings, project-reviews and audits as well as on knowledge management.

German-Iranian trainings create a profitable win-win-situation for the participants as well as for AXI.TECH GmbH. Result should be an optimization of the communication between both parties, the qualification of the Iranian team as well as the possibility for the German team to learn about the Iranian surrounding. Karin Stoller reasoned that pharmaceutical manufacturers who can close their projects to schedule and within budget will have great competitive advantages.

Validation of Process- and Infrastructure Facilities - Dipl.-Eng. Ruth Wohlfahrt concentrated on validation in international standard as well as on several validation strategies, for example the regulatory basis for facility qualification and process-/ method validation, new systems and facilities as well as existing production plants.

Risk Management – The following lecture of Dipl.-Eng. Bernd Geis gave an overview of the GMP labyrinth, focused on risk management and the FMEA method as well as their implementation in Good Manufacturing Practice (GMP). FMEA is a method of the reliability procedure within quality assurance which helps detecting weak spots. This failure prevention avoids follow-up costs by an early detection of the weak points as well as recurring of failures and enhances the technical reliability.

FMEA is AXI.TECH's method of choice to find solutions within the company specific requirements to consider the entire spectrum of design to validation and to contain a great range of application.



Automation and CSV – The implementation of GAMP requirements was the focus of Dipl.-Eng. Ardeshtir Purzadeh's lecture. He gave an overview of computerized systems, talked about validation strategies and cited practical examples, so process control engineering clean media and the clean room monitoring system KIAN, a special product of AXI.TECH GmbH. Furthermore the regulatory requirements FDA, GAMP and Namur came up with regard to the validation of computerized systems.

Biotechnology – Dr. rer. Nat. Zacharias Likidis talked about the optimization of safety concepts and the effect of biotechnology on process technology. In his lecture he divided biotechnology in production stages, like Upstream-Processing, Fermentation and Downstream-Processing, and allotted them to the respective safety concepts.

With this part of the symposium AXI.TECH GmbH completed the presentation of their service spectrum and demonstrated their comprehensive know-how.



The First Biopharmaceutical Customer Symposium Tehran turned out to be an interesting challenge for the engineers of AXI.TECH GmbH which they would meet again anytime, told Dipl.-Eng. Karin Stoller, Head of Quality Assurance and Knowledge Management of AXI.TECH in the interview.

H. Kühn: Which reasons persuaded the AXI.TECH GmbH to orientate themselves on the West Asian market?

K. Stoller.: „West Asia possesses a high culture which was mainly formative in the field of medicine with first basics, even for the European medical science of the 13th century. The present situation of Iran shows the West Asian pharmaceutical market with an ascending potential. By the cooperation of AXI.TECH GmbH and arneg IR, German engineering in GMP environment and an Iranian building company unite on a great growth market, whose increasing demand has to be met. Synergies arise for the future which can capture the West Asian market.“

H. Kühn: How important is the symposium for AXI.TECH GmbH?

K. Stoller: „The symposium provided the opportunity to become acquainted with the West Asian market and to present our name as well as our products and services to the Iranian experts. Personal contacts in the range of industry and university have been established. Cross-cultural competences could be developed and the foundation stone for a productive cooperation could be laid.“

H. Kühn: Have there been any difficulties speaking to an Iranian audience?

K. Stoller: „Among the symposium guests were both men and women of pharmacy and science. The high number of auditors in the hall and the recording of the symposium by the Iranian TV reflected the great interest as well as the significance, which was attributed to the Symposium. The attention paid to us was overwhelming.“



H. Kühn: Which experiences of the Symposium could you take with you?

K. Stoller: „The contact with the Persian culture and the commitment to innovation and performance of the pharmaceutical market makes us look ahead to the future. We are looking forward to a cooperation with the West Asian industry.“

