

Introduction

The establishment of the unit, formerly known as the Hong Kong Pharmaceutical Technology Centre (HKPTC), was initiated in July 1997 with an objective to support local pharmaceutical manufacturers in the GMP implementation program. It aimed at providing GMP and technical support services to meet the needs of local manufacturers so that they could comply with the Hong Kong GMP standard by 2002 and other international GMP standards in the future. The Centre has successfully built up necessary technological components and delivered a variety of GMP and pharmaceutical technical services such as technical information dissemination, GMP document review and preparation, library services, professional GMP training, GMP audits, consultation, and technology study missions to local industry.

Having played a significant role in supporting the local pharmaceutical manufacturers to achieved GMP by 2002, HKPTC combined with our in-house Engineering & Process Design Group and has been reorganized to form the existing unit. Our current GMP services are fundamental to newcomers in GMP implementation. In brief, we offer consultation services mainly in manufacturing facility design, construction management, validation, quality management system and GMP training.

Manufacturing Facility Design

We are armed with extensive experience in the design of manufacturing facilities for biologics, pharmaceuticals, and traditional Chinese medicine. Together with our knowledge on local construction resources, building constraints and regulatory requirements, we successfully helped many companies established their own GMP-compliant manufacturing facility. Factories we have helped to build ranged from 3,000 sq. ft. to 100,000 sq. ft.

In the past years, we delivered numerous facility designs that are used for manufacturing of sterile and non-sterile pharmaceutical products, cosmetics, Chinese herbal extract, concentrate, final formulation, as well as production of herbal beverages. To make your facility as versatile and cost-effective as possible, our facility design service will take into consideration the concept of energy conservation and multi-product manufacturing. Given the fact that the product manufactured may be exported to overseas market, our design service ensures you that the facility will meet international GMP requirement. We used the Therapeutic Goods Administration (TGA) in Australia as a well-accepted international regulatory body in our region.

Construction Project Management

Our service in this area is to ensure our client that the construction of a GMP manufacturing facility is in line with the predefined budget, timeline and quality. Our staff is knowledgeable and has rich hands-on experience. We could reduce your burdens throughout the project life cycle starting with the drafting of tender specification to vendor selection, review of engineering design, monitoring of project progress and quality of workmanship. Our past clients include public hospitals, listed or private pharmaceutical companies and universities. We win confidence from our clients because we provide independent and unbiased technical advice, defining clear expectation from your selected vendors.

Validation Service

Pharmaceutical industry is highly regulated, with validation being a mandate in every aspect of its operation, including all critical facility, utilities, manufacturing processes, analytical methods etc. With our past experience and regional connections with other GMP consultants, we are able to develop and then implement a validation master plan for your facility. We have a spectrum of in-house tools to validate your cleanroom facilities by performing various tests (humidity, temperature, pressure, light intensity, sound level, air particle count, HEPA filter integrity, and bio-burden) followed by written validation report.

The validation service can greatly reduce your cost because you are no longer required to buy and maintain your own set of calibration/ testing tools and train up your people to implement validation.

Quality Management Service

Our consultants have been conducting factory audit to (i) identify defects (physical and operational) to be rectified for an existing GMP plant; or (ii) provide customized consultation service on both hardware and software side of a non-GMP plant if it is to be GMP certified.

In line with the goals, we offer an integrated documentation system including quality procedures, master documents, standard operating procedures, batch production records, and operator instructions. We could also prepare customized GMP implementation program based on client's specific needs.

GMP Training

With the backing of a wide GMP consultants network around the region, we organize GMP seminars / training classes in the principles and applications of GMP in areas such as quality assurance, quality control, and production for local pharmaceutical and Chinese medicine manufacturers. Classes are targeted at both executive and operational technician level.

For-fee Orbital Welding Service

Orbital welding has been the most popular and accepted method for joining 316L stainless steel tubing in the US bioprocessing and pharmaceutical sectors for decades. The new American Society of Mechanical Engineers-Bioprocessing Equipment (ASME-BPE) standard issued in 2002 has been applied to more than 25 countries to make the welding technique more stringent particularly in the areas of documentation and validation. This standard has drawn serious attention from bioprocessing, pharmaceutical and personal care product industries. Our in-house automatic orbital welding system is fully compatible with ASME-BPE standard. The instrument, together with our in-house operational expertise, is available to the industry on a pay-per-use and cost-recovery basis. This arrangement is again attractive to the pharmaceutical industry because they do not require the extra resource to acquire, maintain, train and operate equipment which is used occasionally.

Feel free to talk to us, or visit our website to see how our service can reduce your burden and spending in construction and quality management.

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