COMPANY PROFILE

A one stop consultancy centre.

A1 Consultancy & Integrated Services Sdn Bhd
No. 4-2, Jalan Mutiara Melaka 2, Mutiara Melaka, 75350 Melaka, Malaysia
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1.0 INTRODUCTION

A1 Consultancy & Integrated Services Sdn Bhd., (in short, ACISSB), was founded and started operation in February 2006.

ACISSB offer services in specific areas of consultancy to the pharmaceutical, biotechnology, herbal, traditional medicines, cosmetic, veterinary medicines and food manufacturers. Scope covers regulatory matters, providing technical expertise in GMP related matters, development of system & documentation, training and technical support to target the operational and quality needs of manufacturing industries.
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The strength of ACISSB is our ability to provide quality consultancy services at affordable rates utilizing consultants with years of experience in their relevant fields.

Within a short period of existence, **A1 Consultancy & Integrated Services Sdn Bhd, (ACISSB**), has already extended assistances to various manufacturers in the start-up of the validation activities; from development of a VMP, to basic validation training, to development of qualification plans, schedules, protocol and execution of the qualification work.

ACISSB has also helped few manufacturers to overcome their GMP non-compliances and assist in providing the necessary input to re-activate their suspended manufacturing licenses.

ACISSB is a local company who understands the needs and requirements of local, small and medium industries. We are thus able to meet demands from these industries at a very reasonable fee.

Details information of ACISSB management team is as follows:

Azman Abdul Jalil

Managing Director, Consultant, Trainer.

Holds a Bachelor in Pharmacy (Hons) from University of Al-Mansourah, Egypt. Has 25 years experience in pharmaceutical regulatory & operation, GMP, GSP, documentation, qualification, process validation and production management.

Areas cover from food, cosmetic, herbal, traditional medicines to non-sterile and sterile processing of pharmaceuticals and biotechnology products.

Kartini Dahlan

Director, Administrator

Holds the position of director and has more than 14 years of experience in business management.

Mastura Nordin

Operation Manager, Consultant, Trainer.

Holds a Bachelor in Bio-Medical Science (Hons) from University Kebangsaan Malaysia. Has more than 10 years experience in sterile processing of pharmaceuticals and bio-technology products, regulatory matters, GMP, GSP, documentation, qualification, process validation and production management.

Company Location

The company address is at No. 36-1, Jalan Mutiara Melaka 2, Mutiara Melaka, 75350 Melaka, Malaysia.

Bank Details

1) Public Bank Bhd, Batu Berendam Branch, Melaka
   Account No: 315-001871-8

2) CIMB Bank Bhd, Batu Berendam Branch, Melaka
   Account No: 0405-0000013-101

1.1 STATUS OF COMPANY

A1 Consultancy & Integrated Services Sdn Bhd is a company wholly own by bumiputras with “Bumiputra status” as certified by the Ministry of Finance.

1.2 APPOINTMENT BY GOVERNMENT AGENCIES

Appointment and certification by government agencies are as follows:

a. By Ministry of Finance, Ref. No.. 357-02063111, with Bumiputra status.

b. By MARA as consultant for Industrial Pharmacy, ref. BPU02/15/02-04

c. By NPC as consultant for Good Manufacturing Practise,
ref. (5)dlm.NPC(SMI-AC)807.1/129

d. By SME Bank, as panel consultants in their Central Advisory Services
ref. AC: 911/2 date 18 Aug 2008

2.0 SERVICES

Scope covers industries relating to sterile and non-sterile pharmaceuticals, biotechnology products, herbal, traditional medicines, health supplements, OTC products, cosmetics and veterinary medicines.

Being the only local company providing such complete range of services, we are able to offer professional charges at a very affordable rate and much lower than that offered by foreign consultancy firms.

2.1 Consultancy, Training and Technical Support Services:

- Quality Management System
- Compliance to Pharmaceutical Regulatory Requirements
- Quality / GMP Audit
- Production Management
- Process control
- Microbial environmental monitoring
- Qualification facilities, utilities and equipment for both sterile and non-sterile processing
- Validation of processes and product
- Cleaning Validation
- Documentation and System development
- Application and Registration of products with Drug Control Authority, Ministry of Health, locally and overseas
- Training in GMP related matters
- Stability study of pharmaceutical products
- Facility or plant design for both sterile and non-sterile processing
- Design of Purified water and Water-for-injection system
- Providing technical expertise in procurement of processing equipment

3.1 Designing of manufacturing facilities

Provide assistance and advice on designing of manufacturing plants of sterile and non-sterile pharmaceuticals, biotechnology products, herbal, traditional medicines, health supplements, OTC products, cosmetics, veterinary medicines and food.
Before a suitable layout is developed, a series of discussions will be required to understand the client's needs, requirements and expectations

Activities include:

- Conceptual design on the required facility
- Identifying process, materials & personnel flow
- Proposing (draft) layout of processing facility
- Mechanical & electrical (M&E) requirements (e.g. air quality, water and power requirement)
- Provide input for suitable materials for construction
- Designing of water system such as DI, RO or WFI, inclusive of required piping system
- Design for a suitable waste water treatment system
- Design for a suitable utility system e.g. compressed air, steam, de-dusting
- Designing of facilities for sterile processing: terminal and aseptic processing
- Submission to NPCB (National Pharmaceutical Control Bureau) for design (layout) approval (for pharmaceuticals only)

3.2 Supervision of factory construction

Owners of a facility (factory) may not have competent or knowledgeable personnel to supervision their factory construction work. Some owners may not be able to space their precious time to execute any serious supervision work.

Hence, we are in a good position to provide assistance in this area.

Activities are:

- Provide expertise in supervision and follow-up of the design specifications
- Ensure compliance to structural design specs and M&E specs by contractors
- Helps to liaise with Engineering consultants on rectifying defects detrimental to GMP

3.3 GMP Consultation to manufacturing plant

Not all manufacturers have all the competent and skilled personnel required to execute the various activities in the plant, especially where GMP knowledge is crucial.

In such situation, we are able to offer our technical expertise and experience via a “Retainer ship” program. In this program, we will be bound by a contract to provide continuous technical assistance on any GMP related issues. This activity includes a compulsory one-day site visit and an annual GMP inspection.

For this activity, we are required to conduct the following task:

- As a visiting consultant or retainer
- Through periodic inspection, identify GMP weakness or defects and propose corrective actions
- Providing top management on current status of GMP compliance via contact regular reports.
- Provide GMP expertise in designing and improvement of the quality and documentation system
- Provide GMP in-put in purchasing or procuring of equipment or materials
- Assist in the in-house training program
- Conduct training on critical issues
- Developing of process or procedures in compliance with GMP

As a retainer consultant, we are duty bound to assist in imparting GMP conscious and compliance amongst all levels of personnel, especially top management and managers.

Clients will be charged a minimal monthly fee. A minimum of 12 months period is required for this service.

Any other jobs such as qualification, validation, facility design, etc. are excluded, but can be worked out via a project basis.

3.4 Product Registration

Pharmaceutical products (including health supplement products, OTC, non-sterile dosage forms, sterile dosage forms, vaccines and biotech medicinal products), herbal or traditional medicines and cosmetic products are required to be registered with the Drug Control Authority (DCA) before it can be manufactured and marketed.

Dossiers of the relevant products will require preparation and compilation for submission.

In cases where resources and expertise is limited, manufacturers may seek assistance from consultants.

We are in a position to provide such services. Although this activity is not our priority, we are still able to provide the best and prompt services in order to meet our existing clients' demand.

Activities involved in this service are:

- Providing input and reference on product of interest
- Preparation of documents required for submission in product registration
- Proof read draft labels, product information leaflets and packaging inserts
- Assisting in preparation of product labels and packaging
- Assisting clients of imported products to obtain technical information from oversea manufacturers
- Assisting in developing test protocols
- Assisting in sourcing for analysis of product batch and conduct of stability study, if required.
- We also provide assistance for overseas product registration, such as Singapore.

3.5 GMP Training

Training is one of the most important activities required by GMP. It is the main activity that ensures personnel are constantly updated on their work skill and GMP knowledge.

While most operational work can be trained by internal staff, knowledge and skills pertaining to non-specific issues and general quality matters require external trainers' involvement.

We have the trainers that are capable of conducting training to as many as 30 trainees per one session. Our trainers are competent to deal in matters pertaining to processing operation, process controls, quality assurance, Good Storage Practise, and specific hygiene issues.

We are also able to conduct advance training in areas of qualification, process validation and cleaning validation.

Training can be conducted based on few hours' session, 1-day or two days sessions. For training sessions exceeding one day, a certificate of attendance will usually be given.

We ensure our training program will be beneficial to our client by having pre-training discussion with relevant head of departments, accessing the staff current knowledge and evaluating the existing procedures and system.

Our training program will not be completed without a short test at the end of the session to evaluate staff understanding of the training given.

Activities that fall under this service are:

- Provide training with regards to all aspects of GMP, from basic concept in understanding of quality to documentation, process control and validation
- ACISSB has 11 ready training modules on GMP. *(List of training modules can be supplied upon email request)*
- Providing in-house training program. Our trainings are claimable from HRDF scheme.
- Organize a nation wide Forums, Seminars or Training Modules incorporating speakers from International scene
- One of our trainers is also a part-time lecturer for Industry Pharmacy and Quality Assurance with two of our local University for their Pharmacy students.

3.6 Quality / GMP Audit

For a quality system to be effective there should be an activity to evaluate the system on a periodic basis.

Audit is such activity that is demanded by any quality system, including GMP, as a tool to ensure the system is in control and good compliance at any time.

Audit is required to be conducted at least once a year. Internal personnel can conduct it, but the internal auditor must be knowledgeable, competent and trained in the area of auditing.

Where an organization lacks the competent and trained resources for audit, we are able to fill in this gap. In-fact, audit by our firm will be considered as an independent third party audit that will be free from any risk of bias.

Alternatively, firm may engage us to be part of their internal audit team to enable their internal auditor to be trained on-the-job by our competent auditors.

We are able to conduct both quality audit as per ISO9001: 2000 and GMP.

In this audit activity, the following are carried out:

- Planning of audit
- Review or preparation of Quality or GMP Audit procedures.
- Preparation of audit checklist
- Conduct of audit.
- Evaluation of system that is in compliance
- Identifying defects and weakness
- Proposing corrective action plans

Where necessary, the audit can be conducted in such a manner that allows training of internal personnel to enable them to be competent and trained internal auditors for the firm.

3.7 Stability Study

All registered products, be it pharmaceutical medicines, health supplement products, OTC products, vaccines and biotech medicinal products, herbal or traditional medicines or cosmetic products, require stability study be conducted to show evidence of product compliance to the product quality specification within the shelf-life period.

With cooperation from our associate, such as University Technology MARA (UiTM) and Universiti Kebangsaan Malaysia (UKM), we are able to conduct stability study for any range of products presented to us.

While UiTM & UKM provides the facility for conduct of analysis and proper storage of products during the study, we provide the service in managing the testing schedule, follow-up on test results, preparation of interim or final stability reports and providing feedback to client on status of the stability study done.

Stability studies for registered products are mainly done based on Real Time situation, i.e. as per the NPCB recommended storage condition of 30^0C +/- 2^0C and humidity of 70%RH +/- 5%

For forms requiring research studies on their new products or problematic products, or for the purpose of new registration, an accelerated stability study can be performed at the storage condition of 40^0C +/- 2^0C and humidity of 75%RH +/- 5%

The integrity of stability study thus depends not only on the testing procedures and reporting, but also on the control of the sample storage conditions.

3.8 Qualification of equipment, utilities and facilities

Qualification activity is required for manufacturers of pharmaceutical medicines, health supplement products, OTC products, vaccines and biotech medicinal products. However, currently manufacturers of herbal or traditional medicines or cosmetic products do not require qualification unless the firm wishes to totally adopt PIC/s GMP guideline.

Qualification is required to provide documented evidence that the facility, utility or equipment is able to perform as intended.

We provide assistance and expertise in the most crucial stage of qualification i.e., development of a Validation Master Plan. This plan covers every aspect of the processing plant, from facilities, utilities, equipment to processes, products and cleaning validation.

Our qualification services start from initiation of User Requirements Specifications (URS), right up to Design Qualification (DQ), Installation Qualification (IQ) and finally to Operational Qualification (OQ).

Where performance is crucial to the quality and integrity of products to be processed, we can also provide the technical assistance in conduct of Performance Qualification (PQ).

The process of qualification do not only entails qualifying activities, but includes other salient jobs such as planning, briefing to relevant personnel and contractors, data referencing, documentation, sourcing for testing jobs, verification of data, meetings and so on. All these are included in our qualification package.

3.9 Validation of processes and products

Critical processes, such as blending, heating, filling, sterilization and aseptic filling requires validation in order to provide a high degree of assurance that these processes are able to consistently meet the quality requirements.

With our vast experiences in process validation, be in non-sterile, sterile or even aseptic processes, we have the expertise to provide the required technical assistance in order to get this job done

Jobs relating to this service include:

- Provide assistance and expertise in development of a Validation Master Plan
- Review and re-evaluation of the processes
- Re-development of problematic processes
- Technical briefing, meetings and project management
- Development of protocols for process validation
- Development of a proper documentation system pertaining to validation.
- Development of a suitable sampling plan and sampling procedures.
- Ensuring all relevant equipment and facilities are pre-qualified and fulfill the pre-requisite for process validation.
- Evaluation of necessary external test by accredited agencies.
- Compilation and evaluation of data
- Formulating validation reports

3.10 Cleaning Validation

Manufacturers are required to provide documented evidence that their cleaning procedures for critical equipment and facilities are indeed effective in removal of contaminants.

While it sounds easy, complication arises as most manufacturers have a wide variety of products utilizing a particular equipment and facility. These products may contain active ingredients to as little as 1mg per unit dose, thus making detection of contamination level to be very low.

Furthermore, the contact parts of equipment may present irregularities and difficult-to-clean zones where residues may be trapped and not completely removed during cleaning.

Jobs relating to this service are similar to process validation and includes:

- Provide assistance and expertise in development of a Cleaning Validation Master Plan
- Formulating a cost effective cleaning validation plan where products and equipment are grouped so as to effectively reduce the amount of cleaning validations to be performed.
- Review and re-evaluation of the cleaning procedures
- Re-development of problematic processes
- Technical briefing, meetings and project management
- Development of protocols for cleaning validation
- Development of a proper documentation system pertaining to cleaning validation.
- Development of a suitable sampling plan and sampling procedures.
- Sourcing of suitable materials and test equipment
- Evaluation of necessary external test by accredited laboratories.
- Compilation and evaluation of data
- Formulating validation reports

3.11 Product Development

We perform this service in harmonize liaison with reputable institutions, such as University Technology MARA (UiTM) and Universiti Kebangsaan Malaysia (UKM) on the development of products for registration and market and development of specific test protocols.

With an equipped facility, these institutions are able to provide assistance in developing the appropriate product required by clients. Product may be for medicinal use, herbal medicines or even cosmetic products.

Scopes covered are:

- Provide assistance and expertise in carrying out product development, mainly in formulation of product, packaging and labeling.
- Provide assistance and expertise in developing Test Methods for intended product

3.12 Vendor Evaluation Program

The quality of materials procured is vital to the quality of the final products processed. Materials may range from active ingredients, excipients, labels and immediate packaging materials.

Although quality tests are performed upon receiving, it is more cost effective if the sources where materials are obtained are assured of their capability to meet a minimum quality standard as required by GMP.

For this reason, manufacturers conduct vendor audit and attach a vendor rating to their suppliers in order to facilitate the purchase of good quality materials and assuring of the consistent quality they received.

We are able to provide the technical assistance and expertise in the development and execution of such a Vendor Evaluation program.

3.13 GSP, GMP and Risk Assessment Consultation to Mfg plant

Good Manufacturing Practise (GMP), Good Storage Practise (GSP) are both practical guidance on minimizing the risks associated with manufacturing, storage and handling of pharmaceutical products.

Pharmaceutical manufacturings are all heavily risks related. The extent of how we identify these risks, prioritize them and manage them will determine the smooth problem free operation of the manufacturing plant.

With our years of experience in the field of pharmaceutical manufacturing, we are able to provide technical expertise in the evaluation and assessment of risk to the manufacturing process.

Scopes covered in this service are:

- Conduct of inspection on the processing and storage facilities, identifying GMP/GSP weakness or defects and propose corrective actions
- Evaluation and identifying of risk factors associated with the process, storage and handling of materials and products.
- Work with client in categorizing and prioritizing all the identified risks into manageable grouping.
- Provide risk assessment to determine Critical Control Point in production.
- Assist in the development of a work plan in addressing the critical risk factors
- Assist in the periodic follow-up and re-evaluation of the risk situation

3.14 Microbial environmental monitoring

Other than control on particulate contamination and cross-contamination between different products, another contamination control that is equally crucial in ensuring low microbial contamination to the products being processed.

Various strategies are formulated. One of them is the control of microbial level within the environment, via a good air handling system, a good hygiene and cleaning program and a good control in the handling of materials and products. Since materials and products are exposed to the environment during certain stages processing, this aspect must not be looked down.

Microbial environmental monitoring is cumbersome, as it requires media preparation, good handling procedures and understanding knowledge in microbiology.

A well controlled and monitored environment where the bio-burden is within the acceptable limits present a high degree of assurance during processing of the products.

We are able to provide the technical assistance as well as able conduct microbial monitoring of any pharmaceutical processing facilities; from as non-sterile processing facilities to sterile and even aseptic processing facilities.

Our service extend further to the production of a full report on the microbial status to listing of the probable causes of any failures and finally proposing corrective actions that may be useful to the manufacturer.

4.0 Contact Persons

Note that this profile is able to provide only a short brief and an overview of the services that we are able to provide.

Should you require further information on the above or on any other activities relating to the pharmaceutical industries, please do not hesitate to contact the following persons:

Contact No. 1:

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Company general correspondence:

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End of document.

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