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BIOTECHNOLOGY FOR DEVELOPMENT ORGANIZATION OF A WORKSHOP QUALITY ASSURANCE FOR INDUSTRIAL BIOTECHNOLOGY PROCESSES

October 17-23, 1993
Toronto, Canada
PROJECT XP/RLA/93/098
TECHNICAL PROJECT REPORT

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ABBREVIATIONS AND ACRONYMS

CFR	Code of Federal Regulations
CIDA	Canadian International Development Agency
CTE	Chemical Technology Engineer
cGMP	Current Good Manufacturing Practices
ELA	Establishment License Application
FAO	Food and Agriculture Organization
GMP	Good Manufacturing Practices
HVAC	Heating Ventilation and Air Conditioning
IND	Investigational New Drug
ISO-9000	The International Organization for Standardization
PLA	Product Licence application
QA	Quality Assurance
SOP	Standard Operating Procedure
UNIDO	United Nations Industrial Development Organization
UNICEF	United Nations Children's Fund
WCIP	World Council of Indigenous People

ABSTRACT

This report is a result of an assignment in which UNIDO, Vienna contracted Canbiotech Consultants Inc. to develop and organized a workshop on "Quality Assurance for Industrial Biotechnology Processes". The attendees for the workshop consisted of professionals from nine Latin American countries who are involved in biotechnology research and development, production and quality control activities. The workshop provided a unique forum in which different aspects of Quality Assurance related to the biotechnology process were discussed. Among the main topics were The Quality Assurance Concept, guidelines and regulations, communications, management, design and implementation of effective quality assurance programs.

1.0 INTRODUCTION

The biotechnology industry accounts for over $ 6 billion U.S. in sales in the world today and it is projected that by the year 2000 biotechnology products will reach over $ 50 billion U.S. in annual sales globally.

Successful manufacture and commercialization of biotechnology products requires significant capital and the development of highly qualified human resources. In particular, the specialization and training of the technical and support personnel are key factors needed to achieve product safety, purity and effectiveness.

In general, the Biotechnology industry maintains high quality standards in the development, manufacturing and quality control of its products. Most industrialized countries have regulations and guidelines for GMP which assist biotechnology manufacturers and developers to achieve consistently high levels of quality in their products. In addition, recognized international institutions for quality standards such as ISO-9000 represent a common denominator for product and process quality which are well accepted in the international community.

In the current global environment for biotechnology manufacturing and services the demands for the elimination of error in the manufacturing and control process and the reduction and or elimination of waste are almost essential for the survival of the institutions involved in these types of manufacturing activities.

The quality assurance concept is an essential aid in developing and designing production and its processes through which quality is built-in and maintained throughout, until the product comes into service. However, understanding the quality assurance requirements and methodology for compliance in the biotechnology sector is not easy. As a result, knowledge, as well as awareness of the sensitivities and benefits that the system can provide to the manufacturing process are essential for the success of the QA concept.

2.0 PROJECT BACKGROUND

In April 1993, during debriefing of a field Mission to Thailand for the Project DP/THA/88/018 "Development of The Pharmaceutical Industry in Thailand: Quality Assurance in the pharmaceutical industry with specific reference to process validation", Canbiotech's Technical consultant, Manuel M. Carpio met with several member of the Chemical Industrial Branch of UNIDO in Vienna.

The discussions were focused on the positive impact of the Pharmaceutical Technology Service Centre (PTSC) training activities on Quality Assurance which were conducted in Thailand for professionals involved in the Thai-pharmaceutical industry. The program's objective sought to improve local GMP levels in the pharmaceutical industry in order to meet International quality standards.

The Chemical Industrial Branch of UNIDO indicated an interest in conducting a Technical workshop on Quality Assurance for professionals involved in biotechnology projects in Latin America and the Caribbean Region.

UNIDO appointed Dr. Mayra Sanchez Osuna as a backstopping Officer in charge of the overall coordination of the project and Canbiotech Consultants Inc. from Ontario, Canada were identified as the executing group.

Participants were selected by the Biotechnology Regional Program for Latin America in Mexico.

A detailed technical program and an activity list were prepared by Canbiotech Consultants Inc. and submitted to UNIDO for approval.

Toronto, Ontario, Canada was selected as the meeting place and the workshop was scheduled for October 17-23, 1993.

Canbiotech Consultants Inc. developed and coordinated a "Quality Assurance Workshop for Industrial Biotechnology Processes" in Toronto, Ontario, Canada October 17-23, 1993. This workshop was attended by professionals of different sectors of the biotechnology industry from nine countries of the Latin American region.

The workshop provided a unique forum to explore different aspects of quality assurance related to the biotechnology processes. Quality experts conducted presentations and discussions on the quality assurance concept, guidelines and regulations, communications, management, design and implementation of quality assuance programs.

3.0 PROJECT OBJECTIVES

The project had two primary objectives:

1) To enable participants to gain updated technical knowledge and skills needed to understand the Quality Assurance concept and current requirements for Good Manufacturing Practices in the biotechnology industry.

2) To assist the participants in the development of a comprehensive Quality Assurance Program tailored to the manufacturing, quality control and research and development of biotechnology processes in the Latin American region.

The workshop objectives were:

a) To enable participants to gain up-to-date technical knowledge, which is needed to design, develop and implement technical cooperation, technology transfers and commercial projects in biotechnology in accordance with cGMP guidelines.

b) To review the necessary control systems to secure and maintain Good Manufacturing Practices Standards.

c) To assist participants in identifying and correcting operational deficiencies that can constrain the implementation of a comprehensive Quality Assurance System and cGMP in their operations.

d) To provide exposure to potential problems and solutions associated with technology transfer projects and process plant start-up activities in the biotechnology industry.

4.0 TRAINING METHODOLOGY

The training components of the technical workshop were comprised of the transfer of technical up-to-date information for the design, implementation and maintenance of an effective Quality Assurance program in manufacturing facilities involved in biotechnology processes.

As such, the program included the following areas:

1) A description of the Quality Assurance Concept.

2) Important Elements of Quality Assurance.

3) Quality Assurance Requirements and Regulations.

4) A Quality Assurance System and its organization.

5) The importance of Human Resources Development.

6) The Role of Effective Communications in Quality Assurance.

7) Standard Operating Procedures (SOP's).

8) Management of the Quality Assurance concept.

9) The Regulatory Environment.

10) Plant Design and Start-up.

11) Quality Assurance Case Studies supported with a visit to a cGMP Manufacturing Facility.

5.0 TRAINING FOCUS

The training program was designed for professionals involved in the biotechnology industry.

The program was developed to accommodate up to 15 people.

Toronto, Canada was identified as the focal point for the execution of the workshop and the workshop was scheduled for October 17 to 23, 1993.

Canbiotech assembled a technical team of five qualified professionals to act as facilitators in the different areas of training. In addition, two guest speakers presented specific practical experiences related to the application of Quality Assurance in commercial biotechnology projects.

6.0 METHOD OF APPROACH

The technical workshop consisted of three and a half days of technical sessions conducted by the Canbiotech technical team. During these sessions the different aspects of Quality Assurance and current Good Manufacturing Practices in the Biotechnology industry were addressed.

Throughout the sessions the facilitators reviewed existing quality assurance guidelines and requirements. Key elements for compliance and implementation activities were examined. The sessions were tailored to the needs of the participants with particular emnphasis on the principles for operations and management of quality assurance programs.

A course director was appointed and was responsible for liaison with UNIDO and to the coordinate the technical program.

All participants were supplied with technical information, and visual aids and were given the full support of Canbiotech technical staff.

Verification of the theoretical learning process was obtained by means of having the trainees perform in teams on specific case studies.

For the purpose of case studies and/or exercises the participants were organized in groups of four or five members. Group discussions were encouraged at all times during the sessions.

A workshop evaluation was conducted at the conclusion of the workshop. Completed evaluation questionaires have been submitted to UNIDO.

7.0 WORKSHOP OUTLINE

THE QUALITY ASSURANCE CONCEPT

The Objective of this Presentation was to:

1. Provide an overview of the Quality Assurance Concept through a general description coupled with a historical perspective.

2. Discuss the definitions used in Quality Assurance and their relationship to Q.A. objectives.

3. Discuss the role of documentation and regulations in cGMP compliance.

4. Outline how to implement and validate an effective Q.A. program.

SYNOPSIS - PRESENTATION CONTENT:
The Quality Assurance Concept:

- A Historical Perspective
- The Main Objectives of Q.A.
- Key Definitions
- Personnel
- Facilities
- Equipment
- Materials & Supplies
- Regulations & Guidelines

UNDERSTANDING CGMP REGULATIONS AND COMPLIANCE

The Objective of this Presentation was to:

1. Provide an overview of the cGMP's as they relate to plant design and operation of a biopharmaceutical facility.

2. Discuss the differences between GMP's of conventionally synthesized chemical drugs and those of biologies derived from biotechnological processes.

3. Discuss the role of documentation in cGMP compliance.

SYNOPSIS - PRESENTATION CONTENT:
Understanding cGMP Regulations and Compliance:

1) Regulations as addressed in the Code of Federal Regulations (CFR) parts 211, title 21 referred to as (CURRENT GOOD MANUFACTURING PRACTICES OF cGMP) were covered. This exhaustive list included the following:

- Subpart A:
  General provisions

- cGMP and Pharmaceutical Plant Operation:
  - Subpart B:
    Organization and personnel

- cGMP and Pharmaceutical Plant Design:
  - Subpart C:
    Buildings and facilities
  - Subpart D:
    Equipment

- Control of Compounds and Drug Containers and Closures
  - Subpart E:

Control of compounds and drug product container and closures

- Subpart F:
  Production and process control
- Subpart G:
  Packaging and labelling control
- Subpart H:
  Holding and distribution
- Subpart I:
  Laboratory controls
- Subpart J:
  Records and reports
- Subpart K:
  Returned and salvaged drug products

2) Important differences between conventional drugs and novel biologics with respect to:

- Raw Material Variability
- Product Accountability and Yield
- Process Complexity

3) What are the key elements of a successful biotech facility design?

- Project Planning
- Process Flow Considerations
- Facility Layout Considerations
- HVAC (Heating, Ventilation, and Air Conditioning) Considerations
- Containment Considerations
- FDA involvement in Facility Design
- Validation Considerations

4) **Regulatory Concerns and Issues with New and Evolving Biotechnology Plants:**

- **Multi-use versus dedicated facilities**

5) **General Considerations in the Design of Multi-use Facilities:**

- **Minimizing Cross Contamination**
- **Facility Design**
- **Open versus Closed Systems**
- **Scheduling**
- **Personnel and Training**
- **Equipment**
- **Validation and Cleaning Validation**
- **Changeover (completion) Procedure**
- **Decontamination**
- **Environmental Monitoring**

6) **The Approval Process:**

- **Pre-IND meetings with the FDA**
- **Background and Ongoing Research**
- **IND Submission**
- **GMP Requirements**
- **Clinical Trails**
- **The Product Licence Application(PLA)**
- **FDA Meetings and the Establishment Licence Application (ELA)**
- **The FDA's Foreign Inspection Policy**
- **Managing the FDA Inspection**

EFFECTIVE COMMUNICATIONS IN QUALITY ASSURANCE

The objective of this Presentation was to:

1.0 Provide an overview of the importance of communications in the Quality Assurance system.

2.0 Discuss the impact of communications in human resource development.

3.0 The understanding of the Quality Assurance vocabulary and the cultural interpretations that can cause mix-ups and errors.

4.0 The Standard Operating Procedures (SOP's) and their importance in the Quality Assurance system.

SYNOPSIS - PRESENTATION CONTENT:
The importance of communications in the implementation of a Quality Assurance program:

- **Communications and its impact.**
- **Communication as a key to training.**
- **Communication as a tool to avoid mix-ups and errors.**
- **Understanding the vocabulary.**
- **Written communications**
- **The standard operating procedures.**
  - **Importance**
  - **Instruction**

- Reference
- Documentation
- Compliance
- Control

- New communication technologies.

WORKSHOP OVERVIEW

THE MANAGEMENT CONCEPT

The objective of this presentation was to:

1.0 **Provide an overview of management as its relate to the implementation and maintenance of a Quality Assurance Program.**

2.0 **Review the necessary element for effective management.**

3.0 **The role of human resource development.**

4.0 **Discuss the key element for an effective management program and its implementation.**

5.0 **Importance of Team effort.**

6.0 **Self auditing process**

SYNOPSIS - PRESENTATION CONTENT:

1) **The Management Concept:**

- **Vision and Values.**
- **Needs assessment study.**
- **Planning.**
- **Organizing.**
- **Executing.**

- Controlling.
- Monitoring.
- Evaluation.

2) Human resource development:

- Its importance.
- Team building.

3) A model for continuous improvement:

- The self auditing team.
- The self auditing process.
- Measuring outcomes.
- Elements for continuous improvement.

4) Implementation strategies

- Time tables.
- A cost effective approach.
- Tools for success.
- The required organization.

8.0 FACILITATORS

THE STAFF

COURSE DIRECTOR

MANUEL M. CARPIO, DVM Ms.C, Ph.D., is the President of Canbiotech Consultants Inc., a consultancy company specializing in manufacturing technology and quality operations, human resources development, Quality Assurance and cGMP for the pharmaceutical and biotechnology industry. He has held managerial positions in the biotechnology industry and was in charge of the Technology Transfer group for Connaught Laboratories Limited, Canada's leading biotechnology company and one of the world's largest manufacturers of vaccines. His experience included establishing vaccine manufacturing operations in Mexico, Venezuela and Pakistan.

In the past three years Dr. Carpio has conducted training programs for pharmaceutical and biotechnology companies. Dr. Carpio is also a consultant for the Canadian International Development Agency (CIDA) and The United Nations Industrial Development Organization (UNIDO).

FACILITATORS

Dr. ALEX D. KANAREK, Ph.D, BSC, MCIM., is the former Director of Business Development and was also the Director of the Viral Vaccine Division at Connaught Laboratories Limited, Canada. Dr.

Kanarek has been involved in the manufacturing and licensing of viral vaccines such as poliomyelitis, measles, rubella, influenza, rabies and yellow fever vaccines for Europe, Asia and North America. His experience also includes designing and implementing GMP facilities for bacterial and viral vaccines.

Mr. MAURICE BRYAN B. Com., Communication Consultant, specializes in Communications for Management and Development, Human Resource Development, Adult Literacy and project development. His experience includes journalism, creative writing, Management Information Systems, monitoring communication training projects and human resources development in overseas programmes in Asia, Africa, Latin America and the Caribbean.

Mr. Bryan is a consultant to the Canadian International Development Agency (CIDA), the Food and Agricultural Organization (FAO), the United Nations Children's Fund (UNICEF), the World Council of Indigenous Peoples (WCIP) and the Canadian University Service Overseas (CUSO). He has also been designing and implementing programs and strategies to facilitate planning, institutional strengthening and promoting beneficiary awareness and participation.

ROBERT SLOAN, B.Ed, M.B.A. managed the International operations of Connaught Laboratories Limited. His experience includes sales and marketing management, Materials Requirements Planning (MRP-II), project implementation, inventory management and strategic planning.

Mr. Sloan also has extensive experience in teaching methodology and has published several articles on time management and Total Quality Management (TQM).

Ms. ROSEMINA MERCHANT, M.E.Sc., is a Director of a biotechnology consultancy company providing bioprocess engineering support, project management services, and regulatory advice to the biotechnology industry. Her experience includes process validation, design and implementation of research and development projects, GMP audits, Quality Assurance guidance for industrial fermentation technology, biosafety, fermentation manufacturing technology and recovery of bulk pharmaceutical intermediates and project management.

Ms. Merchant, was a project manager for the Biotechnology Department at the Alberta Research Council, Edmonton, Alberta, Canada with responsibility for scale-up and manufacture of biopharmaceutical products. She was also was a Research Teaching Assistant in the Department of Biochemical Engineering at the University of Western Ontario and at the School of Chemical Engineering, University of Birmingham, England.

PRESENTERS

Mr. SAMUEL A. TELEKI, B. Sc., specializes in Quality Control Documentation and cGMP activities. His experience in Quality Assurance includes protocol administration and GMP audits.

Mr. Teleki was associated with Connaught Laboratories Limited as a responsible head for Manufacturing support services. He is currently involved with a Canadian biopharmaceutical company in the quality control unit.

NIKOLA B. CUCAKOVICH, C.T.E., former director of the Viral Vaccine Division at Connaught Laboratories Limited Canada, specializes in vaccine technology development, processing, scale-up and production technology and biosafety.

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10.0 PARTICIPANTS EVALUATIONS

During the course of the workshop, the participants were given evaluation forms to complete.

Results from the evaluations can be summarized as follows:

Total responses = 10

Time Spent In Attendance was:	Number of Responses:	Percentage:
Very Worthwhile	7	70%
Worthwhile	3	30%
Average	0	0
Of Limited Value	0	0
Of No Value	0	0

In addition, subjects were asked 'which aspects or features of this learning experience were liked the least', with responses generally pointing to a need to increase the amount of "practical" problems/exercises, and case studies, along with an acknowledgement of the lack of time.

Participants were also asked what they would recommend in terms of changes for the workshop. Again, responses centred around expanding the workshop with additional case studies and increasing practical approaches.

Kindly note that original evaluation forms are with the UNIDO officer for this workshop, Mayra Sanchez Osuna.

11.0 CONCLUSIONS AND RECOMMENDATIONS

For biotechnology expertise and knowledge to be exploited fully in an industrial market environment it is essential that a comprehensive and effective QA program be coordinated within a regional regulatory environment and within the individual manufacturing institution. Rigorous standards of safety, purity, effectiveness and quality are of critical importance. The biotechnology industry must maintain particularly high standards of QA throughout the entire product life cycle starting with research and development to quality control of finish products.

Over the past decade, biotechnology advances within the realm of research as well as the development of commercial products have been very rapid. A large number of new products have been introduced by the biotechnology sector to a wide range of market and social activities, particularly within the health care sector. Paralleling the rapid growth of biotechnology base products, there has been a significant increase in the number of regulatory guides and requirements for the manufacture and quality control of biotechnology research and products. International and national authorities issue guidelines to assure compliance with acceptable levels of safety, quality and efficacy of biotechnological products. These directives are usually contained as guidelines for GMP published by the regulatory agencies and are designed to serve as a framework for these regulatory agencies's inspections of manufacturers.

The trend towards harmonization of international regulations and guidelines experienced over the past decade will continue. International institutions for quality such ISO-900 will increasingly set the quality level that manufacturers must achieve in order to participate in the marketplace. In the current global environment biotechnology manufacturers and services must meet cost effective quality levels demanded by international standards. The elimination of errors in the manufacturing and control process and the reduction and, at times, total elimination of waste are essential for the survival of any biotechnology activity.

Latin American and Caribbean regulatory agencies, biotechnology research and manufacturers will increasingly need to ensure that their regulations are at minimum, in harmony with those rapidly evolving in the international arena and that their overall QA programs match the required GLP and GMP to ensure safe, effective and market competitive biotechnology services and products. Manufacturers in the region will need to ensure that their technical and support staff are fully trained to meet and direct activities to achieve QA conformance to a wide range of specifications and GMP standards.

Understanding the requirements for effectively implementing acceptable QA programs which meet various multinational and national regulatory quality standards is a complex and continuous process. The demands for compliancy and other required practices to the various regional and individual manufacturing organizations' is a challenge for all participants within the Latin American and Caribbean region. Human resource development will be a key ingredient in the region's ability to succeed in this area. Training programs among biotechnology professionals will support the region's overall understanding of QA regulations and practices. More importantly, the training will be required to transfer this understanding from theoretical basis to practical application within regulatory bodies and the research and manufacturing entities.

While the concept of QA in biotechnology industrial operations is by now well known throughout the Latin American and Caribbean region, universal compliance may be delayed by factors related to lack of experience and or familiarity with the day to day modalities of implementation.

Many of the issues affecting compliance are related to policy interpretation, human resource development, staff relations, and general management practices as well as the current operational procedures and maintenance of plant and equipment.

Given the presence of additional concerns such as linguistic and cultural diversity, it is often difficult for regional industrial biotechnology plants to independently develop the necessary procedures in isolation, or to envisage the required standard when the models to emulate are scarce or non-existent.

The current moves towards standardization in global trade and efforts to maintain or expand internal markets have reinforced the need to enhance the undertaking of quality assurance practices in the Latin American region. Executive management within the industry are increasingly seeking solutions to current implementation constraints and suitable procedures and training practices which will promote the interest and participation in QA of all levels of staff.

This process requires close co-operation between the various multi and bilateral agencies, institutions and manufacturing bodies as well as the implementation of a regional training scheme which utilize the range of expertise which is readily available in the hemisphere.

As an initial step in this process the recently concluded workshop in Toronto, Canada was able to assemble senior management level staff from 9 different countries in the region to undertake a 5 day training session on Quality Assurance in Industrial Biotechnology Processes.

This workshop focused on key issues affecting Quality Assurance compliance especially those related to human resource development, external and internal communications protocols, system design, implementation procedures and regulatory guidelines.

This workshop addressed specific matters such as the Quality Assurance Concept, Important Elements of Quality Assurance, Requirement Guidelines and Regulations, Important Elements for Quality Assurance Implementation, Auditing, Communications and Project Management.

As a result of the workshop experience, the following conclusions can be drawn:

a) It is widely perceived that there is a need to address further the issue of QA for Biotechnology Processes in Latin America and the Caribbean Region.

b) The QA concept and compliance to international regulations and guidelines is not new to senior technical personnel involved in the Biotechnology field in the region. However, the current modalities for implementation do not consider social, cultural and economic differences existing in the region. QA compliance measures will need to take into account local conditions including social, historical, cultural and economic determinants.

c) Currently there are not too many sources that can provide effective education and training in quality assurance for biotechnology processes in the region. The biotechnology industry and training institutions in this region need to begin the process of developing suitable programs which will convey the need for all-level commitment in the respective organizations and to show the linkage between practice modification and improved results.

Based on the results of the workshop evaluations and discussions the following recommendations are presented:

a) **That UNIDO consider assuming the responsibility of spear heading a project geared to the development of pertinent QA Training programs to achieve compliance in the region. The strategy for development of effective QA programs should be designed step by step to provide a realistic and sustainable conceptual framework, appropriate infrastructural models and suitable implementation plans for universal adoption of QA practices in the biotechnology industry in the region.**

b) **That UNIDO coordinate the undertaking of a feasibility study to evaluate the potential utility of establishing a regional Quality Assurance Institute(s) to develop appropriate materials to be incorporated into existing educational technical training and academic institutions including methodology and human resource development programs tailored to Latin America.**

c) **That UNIDO consider sponsoring projects which support further enhancement and expansion of QA initiatives within the region's academic, regulatory and manufacturing institutions. Projects which could be considered by UNIDO as suggested by workshop participants include:**

- **Facilitate a study of existing plants to identify specific requirements for effective and comprehensive implementation of QA system. Its is essential that such study evaluates current GMP in the region with respect to QA objectives in order to recommend practical actions specific to the regions existing manufacturing practices.**

- **Facilitate an study of existing technical and managerial training programs within the region's academic institutions to identify course content, methodology and data which may be needed to support and enhance QA training programs within the region.**

- **Facilitate the study of the feasibility of establishing a Quality Institute for the region. The institute's mandate would be to coordinate the development of a variety of training programs; the creation of information and documentation centre for the region's biotechnology industry to promote and support effective QA programs among region manufacturers, researchers and technical professionals.**