

Technical Director

BASIC FUNCTION:

The function of a Technical Director is to:

- Develop the formulation of new products as required for BPI customers.
- Develop and validate all associated methodologies surrounding newly formulated products.
- Complete all stability studies necessary to bring a new formulation to production feasibility.
- Develop and validate, to the point of production transfer, all methods and procedures that are required to successfully manufacture and control new products in compliance with all GMP and regulatory requirements.
- Organization of research & development and quality control functions.

The Technical Director will be meeting company expectations of the position when:

- There is success in delivering a pipeline of new products compliant with the BPI standards of quality.
- Successful in implementing a quality control program compliant with current Good Manufacturing Practices as issued by the FDA and in compliant with BPI standards of quality.
- Successful in developing methods and procedures used in manufacture and control of products that are efficient, effective, and lend themselves to the current state of technology at BPI.

REPORTING RELATIONSHIP:

The Technical Director is directly responsible to the General Manager. The Research & Development Chemist and Quality Control Chemist report directly to the Technical Director.

RESPONSIBILITIES

The following are principal responsibilities of the Technical Director:

- a) Enforce and adhere to the codes of the company's Employee Manual.
- b) Ensure that development activities are in compliance with the principals of all-applicable national and international regulations and guidance.
- c) Ensure quality control activities are in compliance with company SOPs

PRINCIPAL DUTIES

The following are principal duties of the Technical Director:

- a) Evaluate the scientific feasibility of new product ideas.
- b) Bring forward, to management, ideas for new products or value-added changes to existing products.
- c) Maintain professional development and industry knowledge to ensure that development projects reflect best current technical practices.
- d) Prepare lab, pilot, and production scale batches.
- e) Fully document and summarize all results, findings, recommendations, methods of manufacture, methods of testing, and any other appropriate items, according to GMP and BPI SOP's.
- f) Project manages and participates directly in the technology transfer of fabrication methods to Production.
- g) Project manages and participates directly in technology transfer of analytical test methods to Quality Control/Assurance.
- h) Order the supplies and capital equipment necessary for operation of the laboratory.
- i) Provide input to the General Manager for operating budgets and capital plans of the laboratory.
- j) Project manages and participates directly in the requisite quality control testing on bulk and/or finished products to adequately demonstrate product compliance.

- k) Project manage and participate directly in the requisite quality control sampling and testing on raw materials to adequately demonstrate compliance to certificates of analysis.
- l) Project manages and participates directly in inventory control of raw materials by properly identifying raw materials in designated areas.
- m) Project manages and participates directly in environmental and water tested as required.
- n) Project manage and participate directly in manufacturing and on-line quality assurance audits.
- o) Perform trouble-shooting of compounded batches.

MEASURES OF PERFORMANCE

1. To the degree that he or she is able to maintain BPI standards of profitability and productivity.
 - a) Produces a pipeline of new products are required by management and some modifications/improvements to existing formulas depending on scientific complexity.
 - b) Operates the Research & Development and Quality Control department within the approved budget and capital plan.
 - c) Demonstrated organizational and project management skills.
 - d) Executed planned new formulations and experiments on schedule.
 - e) Produces a planned quality control program.

2. To the degree that he or she is able to maintain BPI standards of quality.
 - a) Ensures that all work submitted as part of the research & development of new products is accurate correct, and in compliance with all applicable regulatory requirements.
 - b) Ensures that all work submitted as part of the quality control program is accurate correct, and in compliance with all applicable regulatory requirements.
 - c) Maintains and adheres to a valued standard performance for all R&D and QC service activities to designated internal customers.
 - d) Ensures development projects are delivered in a comprehensive fashion such that all requirements and considerations are delivered upon as part of the final product.
 - e) Facilitates the development of solutions to developmental, scientific and quality issues.

3. To the degree that he or she is able to maintain BPI standards of motivation and attitude.
 - a) Demonstrated team spirit, a willingness to help co-workers and displayed enjoyment of the job.
 - b) Works well under pressure and under deadlines.
 - c) Works well in a self directed and self-starting manner.
 - d) Displays an attitude of ownership and accountability for projects and duties.
 - e) Creates and implements positive changes to the new product development process and quality control process and the organization as a whole.

4. To the degree that he or she is able to maintain BPI standards of communication.
 - a) Produces accurate and punctual reports, clearly summarizing the status and direction of developmental and quality control projects.
 - b) Shares information and ideas with others, actively participating in meetings and presenting recommendations.
 - c) Demonstrates good listening skills.
 - d) Communicates well both verbally and in writing.

5. To the degree that he or she is able to maintain BPI standards of problem solving.
 - a) Demonstrates innovation and ingenuity in solutions to technical, developmental and quality control projects.
 - b) Able to resolve technical, human resource and project management situations.

- c) Creates and implements methods of identifying, prioritizing and monitoring progress on issues.
 - d) Willing and effective cross-functional resource.
6. To the degree that he or she is able to maintain BPI standards of technical skills.
- a) Demonstrated desire for development through participation in professional and industrial memberships, associations and courses.
 - b) Gains formulation and production technology intelligence through industrial governmental and professionals contacts, courses and memberships.
 - c) Develops new products in a manner which best utilizes current technical capability and developing industrial standards and technology.
7. To the degree that he or she is able to maintain BPI standards of safety.
- a) Attentive to safety of the work environment.
 - b) Attentive to safety of others.
 - c) Uses and advises others to use safety equipment willingly and appropriately.