

THIS IS AN ORGANIZATIONAL PROPOSAL.



ORGANIZATIONAL TRAINING AND DEVELOPMENT PROGRAM PROPOSAL

November 21st, 2003

To: Quality Assurance (QA) Department

Dr. T.P. Anantharaman, Associate Director of QA
Cesar Smith, Director of QA
Vicki Williams, Vice President of QA
Kim Potter, Associate Director of QA

Attachments: Request For Training Form (**Attachment 1**), Training Module Plan Form (**Attachment 2**), Training Module Approval Form (**Attachment 3**), Post-Training Participant Evaluation Form (**Attachment 4**), Post-Training Presenter(s) Evaluation Form (**Attachment 5**), Standard Operating Procedure (SOP) To Request Training (**Attachment 6**).

* PLEASE NOTE: ALL FULL-SCALE ATTACHMENTS ARE INCLUDED AT THE END OF THIS PACKET (FOR YOUR CAREFUL REVIEW).

Introduction

This proposal is for the preliminary Pharmaceuticals International, Inc. (PII) **Organizational Training and Development Program** project (to be evaluated and launched, if approved, by the QA department under the direction of the Vice President of QA).

This proposal (and the attachments) are *very basic* in nature; this is the first, formal documentation of the ideas generated by Kim Potter and myself, Dawn Rager, during conversations over the last several weeks.

Where the names "Requestor," "Trainer," and/or "Presenter" are used interchangeably, it should be understood that all names represent the individual(s) who requested, initiated, and/or produced the Training Module and material submitted to QA for approval. It is quite possible and probable that many different individuals would be involved in this process (with different levels of knowledge and expertise).

As the writer of this proposal, I welcome all feedback and will gladly meet to discuss and expand on the ideas outlined in this proposal.

I thank you, in advance, for the opportunity to propose an Organizational Training and Development program, here, at PII. I believe we can, together, launch an effective program which can benefit all PII personnel and ultimately, benefit the company, our products, clients, and the consumers.

ORGANIZATIONAL TRAINING AND DEVELOPMENT PROGRAM PROPOSAL (cont.)

Who is this proposed training for?

All PII personnel.

Why?

To inform, educate, train, and develop PII personnel and to encourage personal, company, and product growth and excellence.

What?

The training programs may include, but are not limited to:

- PII "New Employee" training (with the assistance of the Human Resources Manager)
- Job specific training
- Cross-training
- cGMP (Current Good Manufacturing Practices) training
- Safety training
- Basic business communications training (Technical writing, proposal writing, investigation writing, email, client correspondence writing, etc.)
- Crisis-management and problem-solving training
- Motivational team-leading training
- Diversity training

Training By Whom?

Internally by the Organizational Training and Development (OT&D) Manager (with the assistance of department supervisors when necessary and/or requested) and/or other designated PII personnel.

Externally by trainers and facilitators, approved by the QA department (*to be determined*).

ORGANIZATIONAL TRAINING AND DEVELOPMENT PROGRAM PROPOSAL (cont.)

The OT&D Manager Position

The proposed OT&D Manager position will be responsible for:

- Leading teams to access training needs of all PII departments and personnel on a regular basis. The OT&D Manager will meet, monthly, with key department personnel to discuss training needs and to pre-plan for future training.
- Organizing, writing, preparing, and facilitating training.
- Presenting training sessions (when applicable and/or requested).
- Assisting other presenters with training presentations (when applicable and/or requested).
- Evaluating and adjusting all training-related elements, processes, and procedures for improved future training.
- Providing and maintaining all training paperwork.
- Other duties as assigned.

Definitions:

Needs assessment – A summary or report (informal or formal) to define or classify a problem or "challenge" within the PII work environment.

Training Needs – Topics, job positions, responsibilities, and/or other related factors requiring training and education for the promotion of better job performance, production, client, and customer satisfaction. Training needs are determined by a *needs assessment* inquiry.

Training Module – A document and/or form presenting the instructional goals, performance objectives (what participants should be able to do after the completion of training), and format for the proposed training and target audience (including attachments, forms, hand-outs, and other related training material and teaching tools).

ORGANIZATIONAL TRAINING AND DEVELOPMENT PROGRAM PROPOSAL (cont.)

The Process

Needs assessments will be addressed, continuously, within individual departments and by the QA department, to evaluate and troubleshoot problems and challenges incurred on a regular basis, here, at PII.

Needs assessments can be formulated in the following ways, but are not limited to:

- Job performance evaluations
- Standard Operating Procedures (SOPs)
- Investigation reports ("Corrective Actions" to be implemented)
- FDA (and other agency) recommendations
- cGMP policies and procedures

These *training needs* will, then, be brought to the attention of the OT&D Manager and the QA department via a "**Request For Training**" Form (**Attachment 1.**).

Upon review and discussion with the department(s) affected, and with the approval of QA, a "**Training Module Plan**" (**Attachment 2**) will be completed and submitted (by the Requestor and/or other designated personnel) to the OT&D Manager and/or the QA department. After completion of the preliminary training module, the Requestor (Trainer and/or other designated personnel) will review the module with the department(s) affected and the QA department. If the module meets the needs of the training requested and is "acceptable" to all parties involved, QA will approve the training module via the "**Training Module Approval Form**" (**Attachment 3**) and a training session date will be established. *A copy of the "Training Module Plan" and the "Training Module Approval Form" will be returned to the Requestor for the training presentation preparation.*

Personal Note:

"The Training Module Plan" (Attachment 2) is a *basic outline* for the OT&D Manager, department supervisors, and/or other designated personnel to assist in the preparation of training. *It is the writer's belief that training should be presented and facilitated by many different individuals (representing the diversified PII personnel) to provide the most extensive and versatile learning environment for all PII employees. Although not everyone is a "presenter" or "trainer" in heart, or by trade, supervisors and managers can learn (and should learn) how to recognize, address, and evaluate training needs specific to their own areas and specialties. This outline can be a valuable teaching/training tool for others not generally involved in the organizational training and development process. Organizational training and development must be presented and facilitated in a team-oriented approach; a successful program will utilize many areas of expertise and experience for optimal training success.*

ORGANIZATIONAL TRAINING AND DEVELOPMENT PROGRAM PROPOSAL (cont.)

Depending on the material to be covered, the immediate need for training, as well as the manufacturing schedule at PII, a *training session date will be established approximately two (2) to four (4) weeks from the date the QA department approves the Training Module (via the "Training Module Approval Form")*.

Upon completion of the training, a post-training evaluation form called "**Post-Training Participant Evaluation**" (**Attachment 4, F0079.00**) will be issued to all participants. Also, a post-training evaluation called "**Post-Training Presenter(s) Evaluation**" will be issued to the Trainer(s)/Presenter(s) for their comments, recommendations, etc. (**Attachment 5**).

On a short-term basis, all evaluations will be carefully reviewed to improve the content, class materials, and the presentation style of training to improve immediate, future training programs. Long-term training effectiveness will be evaluated by job performance, testing, and re-testing, as needed.

Finally, the OT&D Manager will issue a *"training report"* to the QA department. The training report will summarize the entire training process (beginning with the needs assessment, training module formulation, and ending with the training presentation and evaluations). *The training report "packet" will be kept in the Central Archives (or other designated area) for future training and re-training. This "packet" will include all original training material(s), evaluations, approval documentation, and the final training report. This packet will be accessible to all department supervisors upon request thereafter.*

**ORGANIZATIONAL TRAINING AND DEVELOPMENT PROGRAM
PROPOSAL (cont.)**

In Closing

In order to maintain a sufficiently high profile in the quick-paced Organizational Training and Development area of QA, it is suggested the OT&D Manager will report directly, to the QA Associate Director, *[Redacted]*

Upon approval of this proposal, ongoing evaluations of the training and training request process will be necessary and essential in correcting procedural problems and troubleshooting potential training problems as they arise. As with all new and existing programs, there will be "challenges" along the way... but I strongly believe we can, together, overcome these challenges for a better, more efficient, stronger, and more confident PII.

On a personal note, I have a great deal of organizational training and development skills and experience, and I have successfully supervised and led many team-oriented groups in the processes associated with Training and Development. As a current employee of PII, I have initiated and developed many positive and productive working relationships with many individuals of various departments; I, also, have become familiar with the working environment, processes, and procedures of PII. *Finally, it is my strong belief I can lead and motivate others with excitement, enthusiasm, and experience in launching an efficient and effective Organizational Training and Development program at PII in the upcoming year, 2004, and thereafter.*

Again, I thank you for your careful consideration of this proposal and for the opportunity to share my ideas with you. I look forward to hearing back from you.

Dawn Rager
Dawn Rager, QA Document Change Control

November 21, 2003
Date