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Practice Makes Perfect: Training and Performing in the Pharmaceutical Industry

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ABSTRACT

Within the pharmaceutical industry, there is a constant demand for skilled and qualified professionals at all levels. While getting into the pharmaceutical industry and climbing the corporate ladder is not easy, it can be done. Specifically, pharmaceutical companies and CROs should create career paths that strategically position entry level SAS statistical programmers to junior and then to senior/management level positions. Motivated SAS programmers need to be prepared to meet the growing technical and management challenges.

Initially, a comprehensive instructor led training program needs to be followed by on-the-job training and then effective management and communication classes, for example. This process enables pharmaceutical companies and CROs to successfully grow in this very competitive global environment. The training program and classes need to be based and fully engaged in all three major components: clients working together as CRO partners, products and services helping to reach drug sales goals and employees and managers sharing a common vision. This paper provides insights to best practices in training programs and industry trends for optimal SAS statistical programmer performances.

WHAT IS UNIQUE ABOUT THE PHARMACEUTICAL INDUSTRY?

In 2008, the pharmaceutical industry has become a $50 billion industry with a 10% growth rate (Global Clinical Trials Business Report and Analysis 2008-2018). It is one of the strongest and stable industries, specialized, and highly regulated.

There are many unique things about this industry that continue to attract new talent as well as retain senior level employees. Employees of many pharmaceutical companies have established Mission and Vision statements to chart their career path course. In addition, clinical teams develop game plans to meet study milestones.

For the past few years, pharmaceutical and biotech industries have enjoyed healthy growth that has created a unique opportunity for SAS programmers. Not only did the industry demand an increase in numbers of these skilled personnel, there were also new requirements for more advanced statistical programming skills for tasks such as the identification of difficult study-related data issues, and the programming and validation of more complex tables, lists and graphs.

With a severe shortage of SAS programmers with clinical knowledge and experience and an abundance of skilled SAS programmers from other fields, pharmaceutical companies and CROs needed to reevaluate their staff orientation and training programs to better meet the new environment. To address these changing conditions and requirements, an effective best practices training program was recently developed for new statistical programmers, with special emphasis on servicing the needs of their clients. The goal was that by the completion of a four-week best practices training program, statistical programmers would be more empowered to channel their interest and motivation, while utilizing their analytical programming skills to address clinical study reporting challenges.

Generally, these are the three main categories that uniquely define the pharmaceutical industry: clients working together as CRO partners, products and services helping to reach drug sales goals, and employees and management sharing a common vision.

CLIENTS WORKING TOGETHER AS CRO PARTNERS

To be successful, the client and CRO teams should work as one unit. They should celebrate accomplishments, and develop a good working culture.

In general, clients want to be assured that the statistical programmers on their teams not only have the technical skills, but also the training and experience required to carry out the programming tasks expertly and efficiently by following the client's procedures. Clients have a strong need for statistical programmers who can complete tasks with minimum instructions and supervision. Clients need to know that statistical programmers are not only effective in

debugging SAS programs, but that they also thoroughly understand the clinical trials data. Finally, clients need to feel comfortable that statistical programmers working on their project teams follow their SOPs across all aspects.

To meet these needs, a training program was designed to provide that knowledge and expertise to give the client an additional level of assurance. The best practices training program is very important to ensure consistency in the execution of SOPs. Since client requirements may change over time, it is always useful to update the training program with the latest technologies to reflect current procedures and techniques. CRO programming staff finds themselves working directly on a client's system and using client SOPs. As a result, the CRO programming staff are considered an insource extension of the client since there may only be a difference in the physical location of the team members. See table 1, Division of Client Requirements and Client Teams.

Table 1. Division of Client Requirements and Client Teams

Client Requirements	Client Teams

• Mastery of SAS Programming
• Understanding of Clinical Trials Data
• Program using Data Definition Tables and Program Index
• Program using Table Shells
	• Client Statistical Programmers
	• Insource Extension of Client:
	  ○ CRO Programming Staff
	  ○ CRO Management

With years of experience in bringing new staff on board, our training program was customized to address the current and future needs at a client as well as an individual level. The first step was to identify the types of tasks requested by the client's team. From that, the deliverables were defined along with the process flow to create these deliverables. Finally, the skills needed to complete the tasks were identified – such as working in a Unix environment, or clinical knowledge and understanding. A training program was developed to ensure that statistical programmers were trained in a detailed and consistent manner which met the client's requirements at their satisfaction levels.

Often for critical projects, clients request Key Performance Indicators (KPI) metrics to measure process improvements. Generally, the metrics are quantified and tracked: Quality, Timeliness, and Communication. They are analyzed as individual factors as well as combined for each type of deliverable: analysis data sets, tables, lists and graphs. The objective is to help identify causes of poor quality deliverables or missed due dates if any.

Finally, within the CRO business, it is well established to recognize the four C's for continued success:
1. Capability (Experience/Expertise in therapeutic area) – Can this expertise be built over time? loan to other teams?
2. Compatibility/Alliance (Process/Staff similar to Client for single standardization) - Unified training program?
3. Capacity (Resources/Schedule - timelines)
4. Cost (Comprehensive/Reasonable) – Are employees allocated time to get over learning curve needed to master skills?

Reference: Vogel, J.R., "A Practical Approach to Achieving Success with CROs" (http://www.jrvogel.com/training.html)

PRODUCTS AND SERVICES HELPING TO REACH DRUG SALES GOALS

Within the biostatistics department, examples of products and services include statistical analysis and programming. At a very high level, there are two types of programming assignments: develop and validation. The deliverables consist of analysis data sets, summary tables, lists, and graphs. In addition, other programming tasks may include writing unix scripts to automate program execution, and writing edit checks to identify data issues. In general, team members work from a Program Index excel file to manage and control the deliverables. The Program Index excel file serves to document, drive and inform the manager the status of programming activities. For each deliverable, QC and delivery expectations should be met.

Over time, effective pharmaceutical companies have developed standard macros help to automate common tasks by calling a central set of programs to produce standard tables, lists and graphs. For example, companies may have benchmarking for producing standard tables such as: 10 to 15 simple tables per day or 1 complex table per 2 – 3 days.

Throughout the programming process, each statistical programmer must follow strict validation rules in this regulatory environment.

"Who did what to which data/program, why, when and how?"

One of the main regulatory requirements in the pharmaceutical industry is the 21 CFR Part 11 rule. Essentially, the FDA rule is established to protect consumers from safety issues. The pharmaceutical industry must maintain strict control, documentation, and audit trail of all SAS programs as well as the quality of clinical data. Thorough training records kept on-line with systems such as Learning Management System make it easier to assign new required training modules. In addition, soon CDISC will pose new challenges for the pharmaceutical industry as it is scheduled to become an FDA requirement.

EMPLOYEES AND MANAGERS SHARING A COMMON VISION

Annually and as new employees, performance goals need to be specified. In general, goals should be simple, measurable, actionable, results oriented, and time-based. For clinical projects that are outsourced to offshore companies, additional goals may include improving oral and written communication.

For employees and managers to grow, the environment must be designed to support activities that encourage leadership, communication, and exchange of technical information. At the beginning, new employees get much input from training classes, but should also provide output to confirm training deliverables are acceptable. New employees must be able to demonstrate their skills. As a senior employee, more output is expected, but also should provide input for improving the daily processes as well as the training program. Senior management should actively listen to these suggestions based on employee experience. Always, there should be a continuous loop to provide useful feedback. In general, company goals should have at least 80% utilization rate of training material.

CRO programming staff members have a strong need to understand the motivation behind client requests. They need to be able to get a feel for the clinical trials data to build their confidence. By encouraging the exchange of ideas across various client teams and reviewing new software options, for example, all CRO programming staff benefit during monthly training sessions. Any time spent on mentoring and guiding CRO programming staff is always well worth the initial investment, since they are the single most important resource for completion of the project.

For infrastructure teams that support clinical project teams, often their tasks require the development of tools to help automate the integration of all source data to prevent data duplication and increase data quality. This requires additional knowledge and understanding of metadata. All team members, however, should know why and how clinical data is collected and analyzed to show safety and efficacy.

For external training, CRO programming staff members are encouraged to attend regional or internal SAS conferences to learn about other approaches to common issues or specific workshops to discover new techniques and SAS procedures. Effective pharmaceutical companies and CROs realize the importance for employees to take time to 'Sharpen the Saw'.

CRO management needs to keep client and CRO programming staff satisfied, with a proper balance of training time and production time. CRO management should realize that without the required training, CRO programming staff can not complete vital tasks in a clinical study report submission. CRO management needs to have experienced instructors to create and maintain a thorough training program to address the client demands and communicate this to the CRO programming staff in a user-friendly environment. Trainers can share with CRO programming staff their extensive experience in multiple successful FDA submissions. With the training program and on-the-job experience over a period of few months, staff can rapidly be brought to the level of an experienced statistical programmer. In addition, on-going monthly training sessions also provide continuing education for existing staff. An up-to-date training program along with many years of FDA submission experience provides numerous benefits for the pharmaceutical industry.

Throughout the year, there should be many opportunities to encourage communication of all forms: face-to-face such as one-on-one meetings, phone calls, and e-mails. Ideally, managers meet with each employee at least once every month to discuss progress and any issues. In addition, at least on a quarterly basis, high performance employees should be rewarded and recognized.

Below are some tips for having effective meetings:
- Frequent, focused, future-oriented, flexible
- Document details of each task
- Take minutes of each meeting
- Confirm understanding, expectations, and priorities
- Measure progress towards meeting goals
- Early and often
- Provide feedback
- More important than ever when considering global teams

DEVELOPING AN EFFECTIVE TRAINING PROGRAM

Generally, these are the three main components of an effective training program: training program should meet client requirements, best practices should be applied, and support should exit each career path.

Specifically, a best practices training program needs to include specialized sections such as regulatory processes (the FDA, validation strategies), use of technology (ODS, Metadata, SAS Version 9, Enterprise Guide, Version Control Software) and solutions based on experience (program index, data acceptance tests, clinical data issues). When possible, actual client team documentation or guidelines are used as part of the training program. See table 2, Training Program Meets Client Requirements.

Table 2. Training Program Meets Client Requirements

Comprehensive Training Program Addresses Each Client's Needs
• Set-up instructions for client account access • Training program needs to be consistent with the client's training program in order to understand and apply client's SOPs • Three to four weeks of an individualized program that is intense, self-paced with instructor interaction • Hands-on exercises using real clinical data sets and specifications • Monitor, evaluate, provide feedback on deliverables through code reviews • Comprehensive resource to answer most questions, especially during the first three months on the client's team • Monthly mentor to answer questions from new team tasks • Use any existing client presentation material where available • Enhance client's standard macro user guides with annotated outputs of macro parameters and options

A well-structured best practices training program meets the needs of all three groups: client, CRO programming staff and CRO management. The two main contents of the training program are SAS programming skills and understanding clinical trials data. It is very important for the statistical programmers to have excellent SAS programming and debugging skills as well as exposure to the challenges of understanding the summary and analysis of clinical trials data. See table 3, Two Main Contents of Best Practices Training Program.

Table 3. Two Main Contents of Best Practices Training Program

Best Practices Training Program	Mastery of SAS Programming	Understanding of Clinical Trials Data
Key Objective	• Learn to apply advanced techniques and macros to create reports and graphs. • Learn effective debugging and validation methods. • Learn effective testing and documentation methods.	• Address complex clinical data issues. • Apply correctly primary and secondary endpoints. • Understand drug development process.
Selected Resources (Books, SAS papers, etc.)	• Sharpening Your SAS Skills • SAS Application Guide • ODS: The Basics • The Complete Guide to the Macro Language and Proc Report	• SAS Programming in the Pharmaceutical Industry • Sample Clinical Study
Sample Hands-On Exercises	• Create rtf files using ODS • Validate tables, lists & graphs	• Data edit checks • Create CRTs • Create tables & lists

The training program needs to be an intense three-to four-week training period that is hands-on and practical with multiple interactive sessions to engage the programming staff. The clinical study data sets used for training purposes should be a real legacy study data so that real-world experience can be gained. After the initial day-to-day training program, monthly training meetings should be scheduled for continuous improvement.

For each training section, key questions should be asked of the CRO programming staff to confirm comprehension. In addition, actual SAS programming should be required to complete the training. This enables staff to gain real-world experience in a controlled, learning environment. Since the programming staff will use production macros to create

and validate their tables, lists and graphs, CRO programming staff will need to learn how to apply and debug the client macros.

Finally, because it is often geared for global clients, the best practices training program needs to be portable, standardized and centralized so that each statistical programmer receives the same instructions and materials. In addition, all CRO programming staff members need to have access to the same set of key clinical and technical references for when CRO programming staff need more details on any given topic.

"Behavioral change is required for learning" - David Garvin, Harvard Business Review 1993
"Teaching the employee to perform effectively", Bob Mosher, Learning Guide Solutions 2008
"Plan, Do, Check, Act", Deming

The main focus of the training program needs to be on three objectives: encourage a behavioral change, strive for efficiency, and apply what was learned. In addition, effective training programs meet all five moments of need as defined by Dr. Conrad Gottfredson from BYU:

Acquisition of Knowledge (Formal Instruction)
1. When Learning for the First Time
2. When Wanting to Learn More

Application & Maintenance of Knowledge (Performance Support)
3. When Trying to Remember and/or Apply
4. When Things Change
5. When Something Goes Wrong

With this effective approach, both timing and content are addressed for each employee. For the timing factor, does the employee have time to take the training class and then apply the content immediately? Employees should apply learned content immediately within 2 or 3 months if possible otherwise it becomes more difficult to retain the knowledge. For the content factor, is the content directly applicable to the employee's job responsibilities? Can the employee take advantage of the training delivery method**?** "Research indicates that, on average, less than 30 % of what people learn (in training), actually gets used on the job", Dana and James Robinson, Performance Consulting Systematic Solution: Preparation, Training, Post-training support.

Ideally, guides are available to provide target information at the moment of need. For example, programming tasks should be organized in a flow chart, roles and responsibilities should be listed in job descriptions, and development and validation processes should be explained in how-to and user guides. In addition, effective training programs also make use of informal training as on-the-job training.

CLIMBING THE CORPORATE LADDER

As indicated, each successful pharmaceutical company and CRO should have support for each career path. Climbing the corporate ladder should not be guesswork but well specified with number of years of service as well as increased responsibilities. In general, there are three levels of growth: Entry, Junior and Senior/Manager. An effective training and mentoring program needs to support the corresponding new responsibilities for each level. Training is an investment by both employees and company. For each training objective, action plans such as learning a new programming technique or attending a conference, should be scheduled with due dates.

Table 4 shows the three levels, the position duration and general responsibilities.

Table 4. Titles and General Responsibilities of SAS Statistical Programmers

	Entry	**Junior**	**Senior/Manager**
Title	**Statistical Programmer I**	**Statistical Programmer II**	**Lead Programmer/Developer** **Senior Management Track** **Technical Track**
Duration	First four weeks, first six months	After 2 years	After 5 years
General Responsibilities	- Validation Programming - Edit Checks - Simple Data Listings	- Source Programming - Annotated Graphs - Macro Validation Programming	- Critical Thinker - Global Project Leader - Maintain Program Index - Tools/Macro Development

		- Opportunity for leadership roles	- Effective Delegator

Table 5 shows the corresponding training and mentoring program for each level as well as expectations for each. It is important for the employee to perform beyond his current level before being promoted. The training and mentoring program should be designed to support the transition to the next position.

Table 5. Training Program and Expected Deliverables by SAS Positions

	Entry	**Junior**	**Senior/Manager**
Training and Mentoring Program (Formal, Informal, on-demand, Instructor led, LMS, Hands-on)	- Skills Assessment with Action Plan - Best Practices in SAS Statistical Programming for Regulatory Submission (Continuous Update) - Clinical Data - Analytical Skills - SAS Enterprise Guide Detail feedback and close monitoring (Daily or every other day). Mentor by Senior/Manager	- Skills Assessment with Action Plan - On-the-Job-Training - Internal monthly presentations - CDISC - Teamwork - SAS Certification General feedback and monthly monitoring (One-to-one meetings)	- Lead by Example (Master of skills, sets standards), Mentor - Problem Solver - Effective Writer - Effective Presenter - Good Communication and Collaboration skills Minimum feedback and yearly monitoring (Performance reviews)
Deliverable Expectations	Within 3 days	Within 1 day	Within 3 hours

In general, project teams can consist of up to 20 members. The more team members have a better understanding of why and how clinical data is collected and analyzed to show safety and efficacy, the more they will be able to contribute towards the team's goals. The working environment should encourage independent code review and recognition for excellent service. Based on my experience working on projects, I have found it helpful to maintain a word or excel file containing important notes for each clinical study. Details such as file paths, contacts, program names and status are very important details to keep track of. In addition, as a manager, I maintain a separate file to keep track of employee performance related details. This file becomes helpful during annual performance reviews.

Effective managers need to think systematically. They should have experience in gathering and laying out the necessary data, analyzing the causes of the situation, and proposing actions based on the analysis. More often, leaders have done more homework and know more than junior level programmers. Productive managers have a good handful of attributes, attitudes and habits that set them apart.

RED FLAGS OF POOR PERFORMANCE

How can you identify poor performing employees? Based on experience, there are early 'Red Flags' that indicate more frequent causes of issues and problems. Pharmaceutical companies and CROs need to be proactive by monitoring and taking the following five steps:

1. Enforce strong selection criteria to identify qualified team members before hiring them. Use tools to collect information and make an evaluation: phone interview, face to face, and feedback.

Each person conducting the interview should rate the candidate from strong (5) to weak (1) in the following categories. The final outcome should be one of the following: Consider for Hire, Second Choice, or Reject.

a. Clinical Trials Experience – Task Walk Through – Does the candidate KNOW the Job?
b. Technical skills – Practical Questions – Can the candidate get the job DONE?
c. Communication skills – Proactive? – Can the candidate INTERACT on the job?
d. Teamwork/Department Procedures – Can the candidate follow SOPs?
e. Flexibility/Adapts well to changes – Can the candidate follow detail instructions?
f. Managing Time and Priorities/Planning & Organizing – Is the candidate organized?
g. Thinking Critically/Judgement/Problem Solving 'Challenges' – Can the candidate EXPAND the job?
h. Learning/Initiative – Will the candidate enjoy training process?
i. Leadership/Integrity – Can the candidate answer why the company should hire him?
j. Interest/Sports/Hobbies – Does the candidate have other strengths OUTSIDE of the job?

The phone interview process should consist of screening candidates based on four categories: Technical, Clinical, Communication and References.

A. Technical

For SAS programming, candidates should demonstrate proficiency in topics such as ODS, Proc Freq, Proc Report, Proc Tabulate, Proc Compare, Proc Transpose, Proc SQL, Macros, Data Step Programming, Debugging Techniques, SQL Data Dictionary Tables, Validation, Documentation, Unix, and Graphs.

As identified in the ‘’, SAS programmers should know well the top fifteen topics: Macros, Data Step, Data File Manipulation, ODS, Efficiency, Data Step Vector, Software Development Life Cycle, SAS Resources, Proc Report, SQL Dictionary Tables, Proc Summary/Means, Debugging Techniques, Proc SQL, and Structured Programming Concepts.

For technical assessment, example questions could be:
General -
1. How would you check the uniqueness of a data set?
2. How can you print the format definitions from a format catalog?

ODS –
1. What is the basic syntax for creating rtf files?

Proc Compare –
1. When validating data sets, which one statement is generally required?

B. Clinical

In the pharmaceutical industry, understanding clinical data is paramount. New candidates should confirm knowledge and experience with Lab, AE, ISS/ISE, Edit Checks, Case Report Forms, Missing Values, and CDISC.

C. Communication

As with all industries, communication plays an important role. Strong candidates should be able to explain their technical skills, strengths, weaknesses, challenges, and their goals.

D. References

Finally, references need to be confirmed. Titles and responsibilities for each key position need to be consistent with the resume. Other external information to collect at this stage includes relationship with candidate, history of companies, excellent clinical and programming skills, good team player, would rehire, and their strengths and weaknesses.

2. After orientation, complete an Employee Evaluation form to identify any gaps between employee and position skill set. For each topic below, employees should select one of the four categories: Not Used, Beginner, Intermediate and Expert.

	Not Used	Beginner	Intermediate	Expert
Data Step Processing				
Statistical Procedures				
SAS/Graph				
Report Writing & ODS				
SAS Macros				
Unix				
SDLC				
Drug Development				

3. Complete an Employee Action Plan to complete each gap identified in step 2.

Date	Training	Suggested Completion Date	Completion Date

4. Monitor work habits and behavior to confirm good attitude, communication and hard work. Assure employee strives to deliver excellence.

5. Monitor number, frequency, and cause of missed deadlines. Possible reasons may include misunderstanding of scope of work, procrastination or poor task communication. Such employees may need assistance, for example, to breakdown specifications into workable components or confirm program process flow based on variable calculation formulas.

CRITICAL SUCCESS FACTORS FOR GOOD PERFORMANCE

How can you identify good performing employees? Based on experience, there are five critical success factors that define the elements of a productive biostatistics team.

1. Early team engagement builds trust and relationship which facilitates communication.

It has been proven that employee behavior directly influences customer behavior, and customer behavior directly affects revenue growth and profitability.

"Operating income among companies with high employee engagement improved 19 percent, while it declined 33 percent over the same period among companies with low employee engagement." (Koob, John, Talent Magazine, August 2008)

2. Employee is technically competent to be an independent problem solver. Being SAS Base and Advanced Certified helps to reinforce good SAS programming practices. The new SAS Clinical Trials Certification exam will help to focus on clinical data issues and programming.

From my "Must-Have Tools for Developers" article, I have identified several general resources and solutions for building and managing applications. I strongly believe that all well established SAS programmers should have the knowledge and understanding to complete tasks such as writing a scripting language to automate routine tasks, scan programs and log files, and use SAS Enterprise Guide to help save programming time. In addition, programming style, access to good on-line resources such as example SAS programs and usage notes are also essential. Finally, quality control procedures need to be completed before releasing deliverables.

Usually in the pharmaceutical industry, programming and data issues come up. How good is the employee in summarizing, documenting and identifying the issue to help resolve them? Often an issues log excel file is kept for each clinical study to track the resolution of each issue.

3. Employee is self-motivator to volunteer for more projects and responsibilities and is proactive instead of reactive. Ideally, the employee is very organized, detail-oriented, has a passion for work, and enjoys challenging projects. Productive employees may develop useful macros for repetitive tasks (edit check macros) or checklists for common detail tasks (QC program, checking log). Often these tools can be shared by the team for everyone's benefit.

4. Effective employees understand the 'why' for software development life cycle programming to maintain structure and accuracy of clinical data compliance and content instead of just knowing the 'how' of processing steps.

"Studies on the difference between exemplary and average performers productivity demonstrate dramatic contrasts as high as 200 percent.", Talent Magazine, September 2008. Below are some steps to apply knowledge for increased performance.

1. Cognitive Insight – First exposed to new knowledge/ideas
2. Behavior Change – Accepts and applies new knowledge/ideas
3. Performance Improvements – Improves the process due to better understanding of purpose

5. High achieving employees are constantly raising the bar of standards. These employees self monitor their performance in terms of productivity, timeliness, and quality.

In general, these employees do more of the following for increased productivity:

- Complete more tasks in same time
- Be more detail-oriented in quality of deliverables
- Ask more intelligent questions to improve process
- Assist to more automate the production of standard and simple tasks
- Accept more project related responsibilities
- Have more insight and understanding of data issues

- Is more of an independent programmer and thinker
- Has more variety of programming task categories (Validation, Source Programming, Macro Development)
- Has more skills in SAS programming, Macros and ODS

In general, these employees do less of the following for increased productivity:

- Ask less questions on basic task instructions
- Take less time to complete tasks
- Take less time to resolve analytical issues
- Take less time to resolve programming bugs
- Require less feedback and monitoring of deliverables

SUMMARY

In summary, for pharmaceutical companies and CROs to be successful, their mission statement and values should consider all parties of interest. Employees, managers, clients and partners need to feel comfortable working together on components fully engaged. High achieving employees need to be well prepared and in control of changes in their work environment and expectations.

Mid-year and annual performance reviews can be used to boost morale and productivity as long as goals are measurable, realistic, time-sensitive and attainable. In addition, by asking open-ended questions during meetings, more information can be shared to improve both the employee's performance as well as departmental procedures. Finally, while having good communication skills is the same with other industries, other important unique attributes of the pharmaceutical industry include clinical data, safety issues, and regulatory requirements.

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