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Developing Global Clinical Programming Team with Qualification and Cost Minimization in China

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ABSTRACT

Today many global pharmaceutical companies and Contract Research Organizations (CROs) are building their global clinical programming teams in Asian pie, especially in China. Due to a high demand for talented clinical programmers in China, building a global clinical programming team is a big challenge. Building the team with quality and cost minimization is an even bigger challenge in all the aspects of recruiting, training, roles&responsibilities, communication within internal remote team and external global PRA team, resources management, quality control, lesson&learn, and so on.

This paper will describe the challenges and solutions in building the clinical programming team in Shanghai, Beijing and Wuhan sites at WuXi PRA for the past almost two years.

INTRODUCTION

The Clinical Programming realm is beset by challenges facing organizations looking to partner with service providers both locally and internationally. Many global pharmaceutical companies and Contract Research Organizations (CROs) are trying to identify a feasible solution for low cost outsourcing of clinical programming activities. This challenge is intensified by the opposing objectives of maintaining quality output while minimizing training and on boarding costs. Outsourcing models to achieve these objectives vary widely from company to company.

WuXi PRA is a joint venture between two global CROs – WuXi AppTec and PRA Health Sciences (PRA),which operates independently in China, Hong Kong and Macau and offers comprehensive Phase I – IV clinical development services for pharmaceuticals, biologics, and medical devices and specialize in helping bring innovative, breakthrough products to market. An outsourcing model of Clinical Programming from WuXi PRA was built for PRA in Shanghai, Beijing and Wuhan. One such outsourcing model was described to identify success factors in Clinical Programming Team to face up all the challenges at WuXi PRA in this paper.

RECRUITING

Recruiting is the start point to set up a new function team. In recent years, due to the demands of programmers, recruitment is the first challenge.

How to build a Clinical Programming Team with qualification and minimize on-boarding costs? What are the basic requirement we used in evaluation?

EXPERIENCED PROGRAMMERS HIRED MAINLY IN SHANGHAI AND BEIJING

- Technical skills
- Communication skills with internal team and global team
- Team work internally and globally
- Planning/organizational skills
- Issues discovering and solving abilities
- Experience sharing
- Initiative and ownership
- Leadership

FRESH PROGRAMMERS IN WUHAN HIRED AFTER EVALUATION DURING INTERNSHIP

- Basic Technical skills
- Communication skills with internal team and global team
- Good team player

• Planning/organizational skills

• Initiative and ownership

INTERN PROGRAMMERS IN WUHAN

• Motivation of becoming a clinical programmer

• Education background

• Communication skills in Chinese and in English basically

• Good team player

• Initiative and ownership

TRAINING

FULL TIME TRAINING BEFORE GLOBAL CERTIFICATION

Going hand-in-hand with recruiting is the initial training tasks of "on-boarding". The orientation plan for each level employee was developed to effectively bring the new hires on board. The typical tasks are:

• HR, IT, administration, Finance related training

• Training on policies and SOPs in e-learning system

• Training on working environment system

• Company standard process or template training of TFLs outputs of SAS programming

• Simulating project area training

The orientation plan is based on mentorship program to help with staff development.

INTERNSHIP TRAINING

How can we find a cost effective way to hire our fresh programmer with minimum qualifications? We achieved the goals from our internship training. The evaluation after internship training was the key to help us to hiring qualified fresh programmers. The below process presented our internship training contents:



It was very helpful to enlarge the local talent pool, save bench time and cost, lock in great talents early to WuXiPRA and reduce the resignation rate of fresh graduates.

ON JOB TRAINING AFTER GLOBAL CERTIFICATION

According to the staff profiles, all the staff will continuously receive on job training to improve their capabilities and capacities to the next level after certification in order to maintain all the talents.

- Timely training of improving communication skills
- Training of other functions to have a good comprehensive of pharmaceutical industry or clinical trial
- Continuous training of CDISC standards
- Training of new global standard template
- Intensive training for lead programmer
- Oversea training globally during on-site visiting

It was very helpful to develop the whole team's capabilities, cultivate talents to be lead programmer and maintain the key intelligent team members within team.

COMMUNICATION FOR DAILY ROUTINE

Due to disposition of experienced and fresh programmers in three locations (Shanghai, Beijing and Wuhan), communication is one of critical importance not only with internal project team dispersed in different location but also with global project team in difference time zones. Although face-to-face meetings are much encouraged, they are limited due to time and budget issues. The most-used communication methods involving multiple people are IM, phone call, emails, telecons and alive documentation with share version.

WITH INTERNAL PROJECT TEAM IN DIFFERENT LOCATIONS

A usual set of practices for two project members to achieve their communication goal are IM, phone call within a project team which are direct and easy way to communicate at any time. When we have some pending issues to discuss in a long time, we prefer to telecons or e-mail to involve all the project members in.

WITH GLOBAL PROJECT TEAM IN DIFFERENT TIME ZONE

IM, phone call, e-mail, even telecons are daily ways to communicate not only with internal project team in different locations, but also with global project team in different time zone. An effective way to communicate globally when there exists a big difference between us in time zones is to setup alive documentation with share version for all the comments, feedback or pending issues. After our end, the global team starts to work on the project and can firstly check the alive documentation rather than send each comment, feedback or issue by the individual e-mail. It will be very beneficial for all the project members to know what happened in the project.

In general, communication internally or globally always exists some issues. We will feel more comfortable during each communication if we can improve communication skills with enough training and practice.

MANAGEMENT TEAM SUPPORTS

QUALITY CONTROL PLAN

How to set up the quality control process within function team to grantee we can deliver with high qualify?

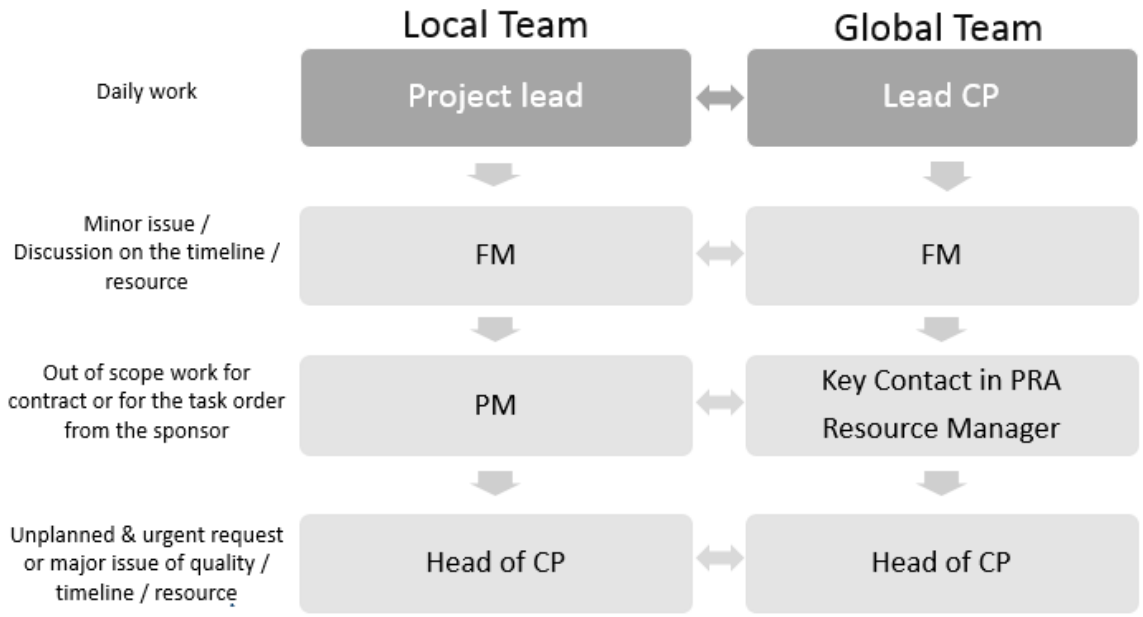
Here are the required item of qualify control plan

- Set up the staff profiles: including the project experiences and the level of QC needed
- Strictly follow global SOPs
- Functional manager perform gate-keeper review
- Training or experience sharing in project team meeting/functional meeting
- Project Initialization confirmation list with global team
- Knowledge share and re-train before project is started
- Lessons Learned

• Issue Tracker and Action Plan

COMMUNICATION AND ESCALATION PLAN

When the critical issue should be face with both global and local team and could not be resolved within the project team, how to communicate and escalate them from management level is as the following flow:



CONCLUSION

In general, there always will be the challenges of recruiting, training and communication when expanding the workforce. Pharmaceutical industry requires a lot of cross functional and cross-site collaborations globally due to outsourcing model to maximize margin and minimize cost.

WuXi PRA succeeded in expanding their clinical programming team in more than past two years, building a qualified global team for PRA in Asian pie and becoming the key component of PRA global capability.

CONTACT INFORMATION

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