**Executive summary**

Varsha Mahajan has worked for Novartis Pharmaceutical Private Limited from July 2001 as a statistical programmer to a Unit Head in a series of different roles within the programming team. Over the years, the responsibilities have increased from an individual contributor under supervision, a trial programmer responsible to deliver at a study level, a lead programmer for a group of molecules, a program programmer managing the submission of the molecule to various health authorities, a Group Head managing large teams across sites and as a Unit Manager managing multiple units with program programmers and group heads reporting in to.

Her 14+ years of experience includes working on clinical trials, summary of clinical safety and efficacy, summary of clinical pharmacology for submissions across health agencies world over, (Data Monitoring Committee) DMCs and (Data Safety Monitoring Board) DSMBs, interim analyses (IAs), health authority questions and publications in various therapeutic areas. Preparation of various submission documents Development Safety Update Review (DSUR), Periodic Safety Update Review (PSUR), Risk Management Plan (RMP), Bioresearch Monitoring Office (BIMO), Office of Scientific Investigation (OSI listings), Briefing Book (BB), Investigator Brochures (IBs), setting up the first CDISC mapping implementation plan for the site for a molecule.

As a Group head for local India team, she has supported the development of the road map for the programming team, define the job roles and career path, create training plan for the team and make team productive. She has set up and developed teams for different Therapeutic areas including phase IV. She has experience as an operational and functional manager conducting performance management and global calibration.

As a program programmer, she has experience of planning, developing and reporting of the submission to Health Authorities with programmers from different sites reporting in to her. Her role included developing programmers for delivering submissions, planning summary of clinical safety, efficacy, RMPs and various submission documents. Interact with Health Authorities via contribution to Briefing Book. Interpret Information Requests from Health Authorities and creating responses for the same. She has been a statistical programming representative in Global Programming Teams. She was instrumental in development of submission coordinators and safety coordinators within the project teams. She has experience in participating in Safety Monitoring Team meetings during assessment of safety of the molecule. She has experience setting up the team ready for FDA inspection and supporting the inspection remotely.

Apart from leading submissions, she has contributed to various non-clinical activities on process improvement, contributing to Standard Operating Procedures and working practices, defining processes and guidance documents for statistical programmers, defining roles and responsibilities for trial programmers in a clinical trial team meeting, audit/ inspection readiness trainings, and guidance document for BIMO and OSI listings, active statistical programming representation in GSK integration.

As a unit manager, she has experience managing programming units with in disease area comprising of multiple molecules going for submission, she has experience managing global teams including their functional and operational management. She has experience being the part of the global leadership team providing strategic inputs in development of the function and the site in general. Bringing on various roles and setting up teams for delivering. Developing road maps, succession plans, creating strategic visions for the function, defining matrices for quality and productivity.

**Key Skills: ICH, GCP training, Six sigma lean project, project management**

**Effective leadership**: 8 years of effectively leading programming teams across sites for statistical reporting for Full development and Phase IV across various therapeutic areas including oncology.

**Programming regulatory experience:** hands on experience of regulatory submissions, planning and preparation of integrated databases and analyses

**Collaboration, Team Building, and Communication:** Interaction with diverse functional groups, training and mentoring interns

**Corporate trainings**

Situational Leadership – 2015

Impact training, The Corporate Athlete, Experience Mindfulness – workshop – 2014

Managing Change - CHX Fundamentals workshop, Contagious Behavior - Be assertive! Communicate with personal impact – 2013

Coaching conversations – 2012

Emotional Intelligence – 2009

M1- Management Leading from Front – 2008

**Professional certifications, trainings**

Advanced Diploma in Software Engineering Honours (ADSEH) Aptech Institute, Mumbai – 1997 - 2001

GCP and SAS trainings

**Educational background**

Executive MBA Welingkar Institute Mumbai, 2006 – 2008

MSc (Statistics) Mumbai University, 1999 – 2001

BSc (Statistics) Mumbai University, 1996 – 1999

**Work experience: Novartis Pharmaceuticals Private Limited (2001 – present)**

Unit Manager – Statistical Programming – Hyderabad, India May 2015 to present

Group Head – Oncology BU – Hyderabad, India Dec 2010 to April 2015

Network Specialist – Hyderabad, India Oct 2009 to Dec 2010

Expert Statistical Analyst– Hyderabad, India Jan 2008 to Oct 2009

Lead Statistical Analyst– Mumbai, India Jan 2007 to Jan2008

Senior Statistical Analyst – Mumbai, India Mar 2005 to Jan 2007

Senior Statistical Analyst – Basel, Switzerland\* Oct 2004 to Mar 2005

Statistical Programmer – Basel, Switzerland\* Sep 2004 to Oct 2004

\*International Assignment at Novartis Headquarters

Statistical Programmer – Mumbai, India Jul 2001 to Sep 2004

**People management roles:**

1. Mid-year and end year reviews of the associates based on the pre-defined objectives, promotion proposals, career development discussions
2. Global program programmer role for a full development molecule (20 people globally – manager of managers) – SCS, SCE, RMP, etc.
3. Global program programmer role for a full development molecule (15 people globally – manager of managers) – development of CSR deliverables, publication requests, Health Authority questions, Additional analysis to support the label claims
4. Group head role for the SAS programming team in various phase of clinical trials (20 people – manager of managers) – full development phase
5. Development of matrix reports, slides for business review meetings across different Line Functions, coordinate managers’ meeting once a week
6. Contributions to the selection of CRO partners by auditing and interviewing them

**Team set-up and development:**

1. Contributions to the road-map for the site specific development of the programming and statistics team
2. Development of the job profiles and career ladder along with other senior managers in the organization
3. Development of fresh college graduates or post graduates from various domains into fully productive independent resources
4. Development of the training material for new joiner SAS programmers

**Project management roles for new drug application submissions:**

1. Manage submission activities for FDA, EMA, Japanese submissions for a few molecules, define the pooling strategy based on the analysis plan
2. Author some sections of the analysis plans for Briefing book for US FDA, Summary of Clinical Safety, Summary of Clinical efficacy, Summary of Clinical Pharmacology, Risk Management Plan, 120 safety updates, etc.
3. Work with the different Line functions like Statistics, data management, clinicians to come up with the analysis plans and timelines
4. Identification of appropriate resources for programming and deliver as per timelines and quality
5. Work on Health Authority Questions, ad-hoc analysis, publication requests, yearly Investigator Brochure updates for molecules in development
6. Contributing to the roles of Independent programmer and essaying the role.
7. Supporting external Data Monitoring Committee (DMC) and Data Safety Monitoring Board (DSMB) analysis
8. Core datasheet update for the label and package inserts

**Clinical trial analysis at study and pooled level:**

1. Started contributions on studies as a support programmer and then gradually increased contributions to a Trial programmer, Lead programmer, co-lead submission activities
2. Review and provide comments on the analysis plan
3. Prepare the programming specifications
4. Pooled analysis of multiple studies in one molecule (one of the many examples)
5. Preparation of the Case Report Tabulation (CRT) for US FDA submission for many studies using an internal tool
6. Various SAS macros – decimal alignment, mixed table, graphs (patient profile style: lab, dosing, death, completion information)

**Audit readiness**

1. Represent the line function in the internal audits
2. Prepare associates across sites for the HA inspections
3. Prepare and plan the mock audits for study close out activities
4. Prepare the Standard Operating Procedures and Working Practices to address the short comings of existing documents

**Technical contributions:**

1. Core member of process revamping for statistical analysis documentation.
2. SME role on various internal systems
3. Contributions as a programming lead to the Standard Output team
4. Contributions to the BIMO dataset initiative, OSI listings
5. Lean Six sigma champion – identification of redundancies in the processes and re-create optimal processes

**People development:**

1. Teaching of basic SAS skills
2. Comparison of a Table vs. Listing vs. Graphs
3. Linking of FDA label to a CSR to individual TLFs in individual studies, in pooled analysis
4. Knowledge sharing sessions for junior as well as senior programmers
5. Interpretation of First Interpretable Results
6. Review of many scientific and technical papers for continuous learning
7. Played a major role in helping a few associates move from one Line function to other to pursue career dreams
8. Development of training material and deliver to a global audience

**Technology and guidelines:**

SAS, Microsoft office, C, C++, IBM Clear Case

ICH and GxP guidelines required for the Clinical trials