Yael Balandrano.

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A: 605 / 150 Liverpool St. Darlinghurst. NSW, 2010.

EDUCATION

Masters of Translation and Interpreting . Mar-2014 – Present
University of New South Wales, Australia.

Bachelor of Business Administration. Dec-1996 – May-2001
Monterrey Institute of Technology and Higher Education, Mexico.

PROFESSIONAL EXPERIENCE

GRUPO LOBO 2000 S. A., MEXICO.

Associate Director Feb-2013 – Jan 2014

- Identified new opportunities of investment for the company.
- Guaranteed that the company performs in compliance with the applicable local regulations.
- Collaborated with investors in the area to develop programs to benefit the community and the entrepreneurial sector.

GLAXOSMITHKLINE.

GSK Biologicals, Mexico.

Quality Control & Training Manager Jul 2012 – Dec 2012
Dec 2009 – Sep 2011

- Developed, implemented and managed a local Quality System for all Phase I – IV clinical trials and epidemiological studies in Mexico in accordance with local laws and regulations, local and global SOPs, and ICH GCP, including the generation and maintenance of relevant SOPs.
- Provided support to the clinical operations team in site management activities from site selection to site closeout.
- Provided training/coaching and support to over 60 staff plus Investigational Sites.
- Implemented a Risk Management System to identify and address existing and potential GCP non-compliance issues across trials.
- Participated in level 1, 2 and 3 audits/inspections from preparation to follow-up of CAPAs with no critical findings.
- Coordinated, developed and implemented Operational Excellence initiatives both local and regional, to increase efficiency in clinical research core activities.

GSK Biologicals, India.

Clinical Operations Manager - South Asia Sep 2011 – Jul 2012

- Provided business oversight, support and solutions to the regional clinical operations in South Asia (India, Sri-Lanka, Bangladesh) through the execution of contracts with local and international CROs, effective planning and management of resources (budget, personnel, investigation sites and internal support services), to maintain successful clinical trial operations.

ABBOTT LABORATORIES:

Abbott Laboratories, Mexico.

Clinical Operations Manager — Apr 2009 - Oct 2009

- Provided clinical expertise and leadership for the conduct of Clinical trials and Post-Marketing studies within different therapeutic areas.
- Coordinated country-specific implementation and execution of clinical studies with respect to (a) feasibility assessment of study protocol, (b) planning and management of resources and budget to meet project goals, (c) deliverables including number of investigation subjects and timelines, (d) monitoring plan, and (e) provision of study tracking data to central teams.
- Managed staff in terms of workload allocation, professional development, performance management, coaching/mentoring, succession planning and talent acquisition.

Compliance and Bio-Equivalence Leader — Jul 2008 - Apr-2009

- Head of Training and Quality Control of the Medical Research department.
- Mentored topic experts to ensure regional presence at the global level.
- Created and successfully implemented Quality System, and global/local SOPs in accordance with applicable guidelines, laws and regulations.
- Facilitated audits and inspections as well as their respective CAPAs.
- Performed ongoing risk assessments in medical research operations to identify performance gaps relative to current regulations and recommend corrective actions.

ELI LILLY AND COMPANY:

Corporate Center, USA.

Lean Six Sigma Black Belt, Intercontinental Region—Medical — May 2007 - Nov 2007

- Identified, evaluated and executed Lean Six Sigma project opportunities.
- Launched, managed and lead projects and teams to execute activities through Lean Six Sigma problem solving methodology.

Eli Lilly Ltd, South Korea.

Sr. Clinical Research Associate, — Jan 2007 - May 2007

- Developed a strategy and programs to efficiently assess, train and coach the clinical operations team (over 30 people) in different trials at different stages.
- Contributed to the successful execution of over 12 Clinical Trials from Oncology, Endocrinology and Neuroscience platforms.
- Performed Quality Assessments of Clinical Trial conduction and management as per ICH-GCP guidelines and SOPs.

Eli Lilly y Compañía, Mexico.

Clinical Research Associate — Jan 2006 - Dec 2006

- Managed simultaneous Phase 3 Clinical Trials to ensure their conduction, registration and reporting to comply with protocol, SOPs, GCPs and local laws and regulations.
- Performed quality reviews and co-monitored with Jr. CRAs to assess their performance.
- Co-created of the 'Voice of the Customer' program, to assess the satisfaction of the investigator sites with the Clinical Research activities performed by the company.

Medical Liaison - Oncology Platform. Sep 2005- Jan 2006

- Participated in affiliate's Brand Councils to present the strategies to develop speakers, speaker tour plans, meetings with the advisory board and opinion leaders.
- Coordinated physician research proposals to build more robust studies and helped physicians with consolidating research ideas in Investigator Initiated Trials.
- Supported physicians through providing up-to-date information about publications, analyses, and abstracts on the latest oncology findings.
- Reviewed visual aids and promotional material to ensure its compliance, accuracy and relevance before their publication.

Clinical Research Associate Apr 2005 - Sep 2005

- Appointed Lead CRA for different phase 3 Clinical Trials at different stages and ultimate accountable for as many as 20 investigation sites.
- Managed, coached and trained Jr. CRAs to meet Clinical Trial goals.
- Collaborated with the development of SOPs as well as regional and global initiatives.
- Created and delivered the presentation of the Medical Research Area during orientation week of new employees in the company.

Jr. Clinical Research Associate Sep 2003 - Mar 2005

- Appointed lead CRA for a Clinical Trial of a new molecule, responsible for initiating and conducting the trial until its eventual transition to other CRAs.
- Trained new CRAs in critical clinical trial processes and business applications (IMPACT, AS400) to aid in the management of simultaneous phase 3 clinical trials
- Collaborated in the preparation of Internal Study Management and Investigator Site Audit resulting in no major/critical findings.
- Collaborated with QC representative in the revision of different SOPs as well as training courses.

Clinical Research Monitor Jan 2003 - Ago 2003

- Conducted and closed-out the longest and largest clinical trial in the affiliate (over 500 patients in an eight-year-long protocol) with exemplary metrics within the region as a single FTE in response to initiatives to boost productivity.
- Completed training to become the Subject Matter Expert of 'Data Management' and 'Serious Adverse Event and Complaint Reporting' to support new and existing CRAs.

CERTIFICATIONS

- SoCRA – Certified Clinical Research Professional (2011 – 2014)
- Targeted Personnel Selection, Development Dimensions International, 2006
- Latin America Advanced Medical Training, Eli Lilly, 2006
- CT MAN IMPACT/POLARIS Trainer, Eli Lilly, 2004
- Latin America Basic Medical Training, Eli Lilly, 2004
- AS400 Data Management Subject Matter Expert, Eli Lilly, 2003
- Data Management Subject Matter Expert, Vienna School of Medical Research, 2003
- Serious Adverse Event Subject Matter Expert, Vienna School of Medical Research, 2003

COMPUTER/SOFTWARE SKILLS

- MS Office (including Word, Project, PowerPoint, Excel, Access, Outlook, Visio)
- CT-MAN IMPACT / POLARIS
- JMP Statistical Software
- Lotus Notes
- CT-FAST, CT-SCAN
- Adobe Photoshop
- Adobe Illustrator
- AS400
- 2WAY Surveying
- iWork (Keynote, Pages, Numbers)

LANGUAGES

- English - Fluent
- Spanish - Native
- Italian - Intermediate