



Michelle Bleckel

OVERVIEW

EDUCATION

Bachelor of Arts, Biology, Purdue University, December 1996 (3.5 GPA)

EXPERIENCE

Supremesoft Corporation (contractor for Hewlett Packard), Columbia, SC Technical Writer (29-Nov-2010 to present)

- * Review the General System Design for a new system against the Detailed System Design documents; check formatting and consistency in ensuring the high level details are the same in both designs.
- * Work with developers and quality to resolve issues.

Eli Lilly and Company, Indianapolis, Indiana

Sr. Procedures/Training Associate – Technical Writer (July 2003-May 2010)

- * Supported site shutdowns by working with all business partners to develop procedures/training for new equipment or processes.
- * Identified potential issues by working with Document Owners and Quality; determined a course of action to ensure efficient, effective compliant documents.
- * Developed new processes for ensuring efficient, effective and consistently compliant procedures/training while collaborating with other departments on Six Sigma projects and kaizens.
- * Managed the 3-year review and the integration rollout project, along with multiple other projects, by assigning responsibilities, tracking progress, establishing timelines and collaborating with management to ensure objectives were met or exceeded.
- * Generated and reported activity based management and usability test metrics.
- * Interpreted and related Quality standards during all procedure/training revisions.
- * Worked within all Code of Federal Regulations and FDA pharmaceutical guidelines for Good Manufacturing and Laboratory Practices; also monitored and checked the U.S. Pharmacopeia to ensure Lilly Quality Standard compliance.
- * Created and facilitated a monthly team meeting to evaluate situations and propose solutions as well as create consistency in processes as a way to influence change.
- * Performed usability tests on procedures/training by observing and documenting the processes with subject matter experts and Quality.

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- * Mentored new personnel; called upon to represent the department and provide input/guidance.
- * Prioritized workload effectively while working independently.

- * Accountable for behaviors as described in Lilly's Redbook.

Associate Microbiologist (April 2000-July 2003) Kelly Technical Services temporary (1999-2000)

- * Analyzed samples according to validated methods and reported data in ADMIN/LIMS.
- * Investigated suspect results in microbiological and purity testing labs.
- * Validated purity methods for clinical trial drugs and ensured current validated methods were accurate by collaborating with the method development department.
- * Worked within all Code of Federal Regulations and FDA pharmaceutical guidelines for Good Laboratory Practices; also monitored and checked the U.S. Pharmacopeia to ensure Lilly Quality Standard compliance.

Universal Flavor Corporation, Indianapolis, Indiana

Associate Beverage Technologist (1998-1999) Lab Support temporary (1997-1998)

- * Prepared production directions, nutrition facts and ingredient statements for beverages.
- * Visited customer sites to observe production runs.

**Seradyn, Indianapolis, Indiana (Lab Support temporary)
Process Coordinator (1997)**

- * Scheduled and supervised production lines that filled, labeled, and packaged diagnostic kits.

ADDITIONAL WORK ACTIVITIES

- * Updated/performed maintenance on mainframe software packages to align with user requirements.
- * Developed training for on-line viewing of reports; performed training.
- * Compiled monthly and yearly reports and forecast data.
- * Customer service contact/subject matter expert for all positions to ensure all complaints/problems were identified and resolved.

COMPUTER SOFTWARE USED

Microsoft Word, Excel, Lotus Notes, Outlook, Internet, Sharepoint, Regulus, TrackWise, LEADS, Adobe, etc.

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