Scott J. Miller **www.linkedin.com/in/millerscottjoseph**
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Knowledgeable biotechnology professional experienced in developing, marketing, and manufacturing biotechnology products. Highly proficient in design transfer, process improvement engineering, project management, reagent production, technical writing, and verification and validation activities. Adept at implementing best practices in achieving continuous improvement, design control, marketing, quality assurance, and regulatory objectives.

Skills

- Change management
- Critical material assessment
- Design control
- Document change control
- Material specification development
- Product transfer
- Project management
- Quality assurance methods
- Quality improvement & tracking tools
- Reagent development & production
- Regulatory-compliant writing
- Risk analysis methods

Education and Certifications

American Society for Quality Certifications:
Biomedical Auditor (2011) ● **Quality Auditor** (2010) ● **Quality Process Analyst** (2009)

B.A. Biology, 2004, Roanoke College, Salem, Virginia

Experience

Canon BioMedical

Technical Marketing Writer, Marketing October 2015 to August 2018

Catalyst to the commercial operations team responsible for the creation and management of all external communications. Led the media relations of Canon BioMedical's accomplishments to the outside world and within a complex, global organization. Managed the three-member internal agency to produce web, social media, and video content.

- **Created the brand and voice of Canon BioMedical** as Canon entered the life science market. Led workshops to build a comprehensive voice and style guide for internal and external use.
- **Oversaw the creation of all content** to support product launches and marketing campaigns. Guided the Marketing team in distilling their key messages to create high-impact content (flyers, infographics, social media, etc.) to engage customers. Authored user guides, package inserts, scientific posters, software user manuals, and other technical documentation required to utilize genotyping assays.
- **Led the planning and resource allocation** of company personnel and freelance contractors. Selected external agencies and freelance contractors, negotiated contracts and rates, and managed external partners to produce thoughtful content.
- **Ensured materials were provided within 30 days** of request while increasing the 2017 output by 56% over 2016. Onboarded and trained new technical and marketing writer (TMW) in 2018 to meet increased demands.

QIAGEN September 2005 to October 2015

Technical and Marketing Writer, MDx Marketing Excellence June 2014 to October 2015

TMW responsible for the creation and project management of compelling marketing materials and user-oriented technical documentation to support the infectious disease and women's health programs (~$300 million in sales; 25% of revenue). Managed a team of freelance writers to deliver technical materials.

- **Advanced a new focus** on customer needs as a brand champion supporting key growth drivers. Created new marketing materials and online content to drive the message of QIAGEN as a global, premium provider of molecular diagnostics. Supported teams in achieving goals for instrument placement and menu growth.
- **Managed the technical literature** required to launch multiple molecular diagnostic products in numerous markets. Supported Regulatory Affairs teams in achieving approvals and clearances from regulatory bodies (FDA, Health Canada, ENVISA, etc.) for multiple assays (HBV, HCV, HIV, HPV, MRSA/SA).

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Specialist III, Quality Assurance — April 2013 to May 2014

Specialist II, Quality Assurance — January 2012 to March 2013

Technical writer responsible for the creation and content of user literature required for Class III IVD medical devices in accordance with 21 CFR 820 and 809; IVDD 98/79/EC. Member of product development teams and Technical Literature Consolidation Team functioning as an expert in medical device product requirements.

- **Managed the technical literature** required to successfully launch multiple molecular diagnostic products (*care*HPV test and instruments, QIAsymphony DSP HPV Media Kit). Coordinated with stakeholders to ensure the availability of all required design outputs within short timelines. Authored and formatted multiple documents in compliance with the corporate image guidelines including instrument user manuals, product inserts, protocol sheets, training guides, and other requisite product literature.
- **Collaborated with cross-functional teams** to determine product scope and accurately reflect device specifications in the design history files. Served as the Quality Assurance representative on product development core teams and established labeling strategies to comply with the many regulatory environments required for a multiple-market product launch.
- **Advanced the simplification of user documentation** to improve safety, streamline content, eliminate redundancy, and ensure corporate branding in instrument labeling; investigated ambiguities in the technical literature. Effectively achieved agreement from various regional operations and marketing units on the implementation strategies for releasing updated documents.
- **Interfaced with the global TMW team** to collaborate on technical challenges, streamline document development, and improve the corporate image guidelines. Instituted a department wiki to document work instructions and trained teammates on SharePoint functionality.
- **Supervised fellow TMW** assigned to create multiple user manuals as part of a multi-million dollar, two-year IVD instrument development project. Reviewed outputs and assisted in constructing accurate timelines for deliverables in preparation of customer placements and investigational device exemption (IDE) submission.

Specialist, IVD Documentation, R&D Americas — January 2010 to December 2011

Documentation specialist responsible for the development of medical device documentation. Member of project core teams, design transfer teams; contributor to Design Control Task Force; department expert on critical materials assessment.

- **Led departmental initiative** to redesign the risk analysis and classification of critical materials. Gained approval from directors and Quality Assurance department for a new cross-functional SOP within the global design control procedure. Instructed senior management on the procedure implementation and templates.
- **Established device master records (DMRs)** for products developed under design control, including 150+ manufacturing master records, SOPs, material and label specifications, and quality control acceptance procedures. Recognized by scientists for recommending process improvements during procedure capture.
- **Reviewed supplier evaluation and qualification documentation** to guarantee suppliers were capable of providing materials of sufficient quality and volume to support commercialization. Assisted with supplier audits.
- **Ensured FDA-compliant document change control** for all R&D DMR documents, including maintaining document repositories in OpenText LiveLink ECMS and Microsoft SharePoint and training end-users in documentation change control policies and procedures.
- **Championed new design transfer processes** and achieving successful review of 150+ DMR documents during technology transfer from R&D to Operations. Supervised team members in national and international regulatory labeling requirements, good documentation practices (GDP), and understanding scientific principles.

Scientist I, R&D Product Development — August 2008 to December 2009

- **Identified optimal materials and suppliers** based on product specifications by leading both material quality and supplier quality investigations in coordination with Supplier Quality team. Guided team members on cGMP and GDP to achieve successful verification and transfer of reagent production processes.
- **Advanced reagents of a sample preparation kit** from bench formulations to commercial product produced at a scale required to meet forecasted demand. Composed and presented design review documentation progressing production processes to the next development phase.
- **Guided team members** on cGMP and GDP to achieve successful verification and transfer of reagent production processes. Identified optimal materials and suppliers based on product specifications through material quality and supplier quality system investigations.