Katia Russoniello, RN, BSN, MPA

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SUMMARY

Registered nurse with 15 years of international and domestic pharmaceutical industry experience focusing in Pharmacovigilance (device and drug), litigation review, global medical affairs, medical writing, product labeling, promotional review, Clinical studies and site training with 36 years in healthcare. Experienced in following therapeutic areas: Cardiovascular, Respiratory, Anti-Infective, Women's Health, Osteoporosis, and Anti-fungals.

- Exceptionally strong clinical and pharmaceutical knowledge base/background
- Successfully direct projects from concept to operational status. Effectively communicates mitigation strategies in matrix organization to ensure successful project implementation. Decisive leader/team player.
- Proficient in understanding, interpreting and evaluating clinical data.
- Demonstrates strong presentation, communication and leadership skills to manage cross-functional initiatives.

PROFESSIONAL EXPERIENCE

Ikaria Inc.
Hampton, NJ
Drug Safety Specialist, Pharmacovigilance ***Sep 01 2014 to present***

- Triage cases by reporting criteria, expedited reporting vs periodic reporting, based on an understanding of "seriousness" and "expectedness" criteria.
- Carefully assess adverse events (AEs) and medical device complaints received from post marketing sources and prioritize workload to ensure compliance with regulatory reported responsibilities.
- Follow up with reporters for missing relevant information or event details needed to facilitate adverse event or device case reporting.
- Working knowledge of sponsor database (ARGUS), good understanding of data entry conventions and have expertise of search functions in the safety database.
- Enters safety data into the sponsor database (ARGUS) utilizing MedDRA to code clinical events, medical history, indications, and WHODRUG dictionary to code medications. Ability to interpret the received report sufficiently to complete all necessary fields.
- Authors highly comprehensive draft narrative for Post-marketing spontaneous and device reports (including literature reports) utilizing standardized narrative templates.
- Ensure regulatory compliance with timelines for submission of individual expedited case reports (drug and device) and distribution of all serious adverse event reports to affiliates.
- Responsible to answer Adverse Event phone line during company business hours, gather and record provided information accurately.
- Assist in the development and update of departmental process guidelines and work instructions.

BioPoint consulting
Ikaria Inc., Hampton, NJ
Drug Safety Associate, Pharmacovigilance (consultant) Mar 31 2014-Aug 31 2014

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InVentiv Health Clinical
Bayer Healthcare Pharmaceuticals, Whippany, NJ Dec 9 2013-Mar 30 2014
US Pharmacovigilance, GPV
Medical Record Extractor (consultant)

- Analyze and extract pertinent case information from medical records received for Women’s Health cases in U.S litigation per Food and Drug Administration (FDA) regulatory guidelines and Bayer SOPs.
- Reviews medical record follow up to cases in litigation in accordance with US FDA Regulations.
- Reviews legal complaints and/or summons and case entry into Argus Local Affiliate module (LAM); performs QC.
- Conduct CRO (Contract Research Organization) oversight to ensure high quality cases in alignment with SOPs.
- Authored comprehensive narratives procured from relevant legal case documents and patient medical records
- Updated narratives created from AE database to ensure accurate reporting of data.
- Code AEs, medical history, indications and concomitant medications using MedDRA and WHO Drug Dictionary.
- Perform Quality Control checks to ensure accuracy of extracted medical data.
- Receive and evaluate adverse drug reports for processing within specified FDA timelines.
- Analyze AE report documents for the accuracy of case reports by identifying problems, omissions/inconsistencies of patient identifiers, conflicting histories, AEs, or inaccuracies in therapeutic procedures or drugs.
- Prioritize and triage time-sensitive cases to Safety Data Coordinator in a fast paced environment to ensure compliance with Bayer case processing and local and international regulations.
- Responsible for closing action items to cases in litigation.

SKG consulting
Daiichi Sankyo, Edison, NJ
Clinical Development Jan 3 2012- Nov 26 2013

Senior Clinical manager-Medical (consultant)

- Exceptionally strong clinical and pharmaceutical knowledge base/background.
- Provides an exceptionally high quality medical review for 4000 narratives, as required for FDA Submission.
- Coordinate efforts with Medical Operational Manager to develop and update narrative conventions/QC checklist/Medical reviewer QC checklist.
- Identify issues and trends in draft documents that require updates to the narrative conventions.
- Authors' comprehensive narratives, provides revisions and makes corrections to sample drafts written by proposed writers from Quintiles/Medpace and provide accurate timely feedback to Medical Operational Manager.
- Provide regular updates to the Senior Clinical Medical Monitor/team on quality of narratives and progress; solicits guidance and provides training for process improvement, as needed.
- Interact with the regulatory team on narratives and coordinate with operational manager for publishing and hyper-linking of the narratives.
- Collaborate with various clinical team members on startup narrative activities for the Hokusai study as well as provide medical review of other study submission documents included and not limited to coding on ad hoc basis.
- Created and executed training workshop/lectures for the position of medical reviewer.
- Recognized as a senior team member of the medical review narrative Engage project, that completed an exceptionally high quality medical review of narratives, responded to QC within set timelines, and finalized 4265 narratives, meeting the deadline of the 7 weeks' timeframe post DBL.

Joule Staffing
Bayer Healthcare Pharmaceuticals, Wayne, NJ 2011-Jan 2 2012
US Pharmacovigilance, GPV
Medical Record Extractor/PV Case processor (consultant)

- Authored comprehensive narratives procured from relevant legal case documents and patient medical records.
- Member of the QC Team responsible for ensuring accuracy of extracted data and compliance with departmental policies.
- Updated narratives created from AE database to ensure accurate reporting of data.
- Conduct CRO (Contract Research Organization) oversight to ensure high quality cases in alignment with SOPs.
- Code AEs, medical history, indications and concomitant medications using MedDRA and WHO Drug Dictionary.
- Analyze and extract pertinent case information from medical records received for Women's Health cases in U.S litigation per Food and Drug Administration (FDA) regulatory guidelines and Bayer SOPs.
- Perform Quality Control checks to ensure accuracy of extracted medical data.
- Receive and evaluate adverse drug reports for processing within specified FDA timelines.
- Analyze AE report documents for the accuracy of case reports by identifying problems, omissions/inconsistencies of patient identifiers, conflicting histories, AEs, or inaccuracies in therapeutic procedures or drugs.
- Prioritize and triage time-sensitive cases to Safety Data Coordinator in a fast paced environment to ensure compliance with Bayer case processing and local and international regulations.
- Recognized as an exceptional team member (Medical Record Extractor/PV case processor team) in the promotion of the companies central core values: Leadership, Integrity, Flexibility and Efficiency; summarized by the term LIFE. Senior management of medical extractor team received LIFE award and team was recognized as the contributor.

Merck & Co., Whitehouse Station, NJ **Jul 1998 – Oct 2010**
Global Medical Affairs, GHH
Product Scientific Specialist/Product manager *Nov 2009 – Oct 2010*

- Reviewed, evaluated and approved contents of promotional materials and publications. Ensured information, claims and comparisons were medically and scientifically accurate, compliant with company guidelines, clinically relevant, presented in appropriate context and were in accordance with regulatory agency guidelines, codes of practice and company policies and procedures for ZOCOR, CANCIDAS and NOXAFIL for internal and external customers.
- Co-authored 5 modules for medical education in the area of infectious disease (antifungal) products.
- Co-authored selected safety information [SSI] for products in the US, EU and ROW, for use in product-related promotional materials for ZOCOR, and CANCIDAS.
- Member of Medical/Legal review team with strong clinical background and medical terminology.
- Identified emerging medical trends, marketplace issues (e.g. Medical Inquiry Trends, Business Served as Subject Matter Expert to develop key parameters when negotiating vendor contracts Intelligence) and quality assurance issues and share with appropriate personnel.
- Developed standard/unique Professional Information Request (PIRs) and responds daily to medical inquiries/customer service.
- Negotiated with key stakeholders in marketing, legal and promotions to ensure timely execution of product objectives (both international and domestic).
- Liaised with internal and external clients and colleagues to communicate required medical changes to scientific documents with rational and recommended improvements in promotional material at US and Global/Medical/Legal Review Boards.
- Collaborated and partnered with marketing teams and extended team members including Product Leaders, Legal Services, Clinical Research, Marketing Communications and external agency personnel to support comprehensive and efficient reviews in the development of global initiatives and promotional messages for ZOCOR, CANCIDAS and NOXAFIL.
- Developed departmental SOPs for Operational implementation for departmental website.
- Authored medical abstracts from publications and updated scientific concepts by performing literature searches, and communicating the information in a timely manner. Responded to over 100 Professional Information Requests from external health care professionals. Working knowledge of IRMS (Information request management systems).
- Conducted root cause analysis of promotional review process to increase efficiencies and decrease timelines.
- Received, analyzed and documented reports from HCP (Health Care Professionals) of possible adverse drug reactions. Triaged to Clinical Risk Management and Safety Group for processing.
- Educated Marketing personnel (pharmacists, PharmD) in the Anti-fungal therapeutic area and labeling/indications for CANCIDAS.

Award of Excellence 2010: Marketing and Leadership Principles: Recognized for collaborative effort in the co-development and authoring of PSS (product scientific specialist) new employee roles and responsibilities guide, with website linking, implemented (Oct 2010).

Merck & Co., Rahway, NJ
Clinical and Product development
Associate Clinical Research Specialist/Scientist *Jan 2008 – Nov 2009*

- Co-authored clinical protocols (Phase III), Clinical Development Plans, federal regulatory documents, narratives, abbreviated CSR, and other scientific documents.
- Managed trial activities for assigned projects, including concept submission, informed consent form, case report forms, clinical study reports and timelines. Negotiated study contracts and budgets.
- Operated within a matrix environment to carry out the conduct of specific trials. Ability to handle multiple priorities efficiently, with excellent telephone skills and follow-up.
- Medically monitored patients enrolled into clinical studies in real time and reviewed aggregate data for safety and efficacy trends. Member of medical monitoring team (MTT).

- Worked independently and in collaboration with vendors/clinical management systems: ICON/PPD/CTMS/IVRS/TMF/ALMAC.
- Utilized EDC (electronic data capture) in trial management, co-developed and authored eCRF's.
- Communicated with investigator sites to resolve data discrepancies and coordinated error resolution with site managers utilizing knowledge of safety reporting, good clinical practices (GCP/ICH) and regulatory compliance and SOPs.
- Provided training to subsidiaries/sites that support clinical study.
- Working knowledge of clinical database systems-INFORM. Experience and knowledge of basic MS office computer programs, excel, and PowerPoint.
- Conversation ability in another language (Byelorussian/Russian).
- Co-authored Trial Newsletter for study, highlighting significant information to facilitate study globally.

Award of Excellence: Marketing and Leadership Principles Recognized for collaborative effort for 2008 Pediatric sWMA approval for CANCIDAS.

Merck & Co., Rahway, NJ
Regulatory
Worldwide Product Labeling
Regulatory Writer *2002 – 2008*

- Key member involved in the process of reviewing, developing and coordinating approval of a US label, EU and ROW, which reflects the Company's medical and scientific knowledge on its products. Interact, facilitate and communicate clearly with multidisciplinary team members (regulatory, marketing, CMC, clinical, legal) to develop and write US/Headquarters' product labels while maintaining scientific rigor.
- Facilitated the resolution of issues by organizing and chairing Worldwide Product Circular Review Committee (LEAD) meetings, VP (LAST) meetings and initiate effective communication with Regulatory Managers worldwide.
- Coordinated, prepared and submitted draft US labeling for submission to the FDA to comply with FDA regulations.
- Prepared and released headquarters documents (sNDA, Centralized Procedure Variations, FPLs and SPLs) with updated labeling text meeting post-marketing clinical and safety requirements (CBEs and AERT). Familiar with projects for Compassionate Use. Member of AERT review team.
- Co-authored PADR and ADR for CANCIDAS, MEFOXIN, NOROXIN, INVANZ, CRIXIVAN and CUPRIMINE.
- Co-authored labeling text and Completed major efficacy Pediatric filing with FDA physician labeling reformatting for CANCIDAS-2008.
- Motivated team members/a self-starter with ability to develop collaborative relationships with diverse clientele.
- Designed, developed and implemented Policy and Procedure guidelines for department.
- Interviewed prospective candidates for various positions within the Worldwide Product Labeling Department.
- Participated in first MedDRA update to CANCIDAS and NOROXIN labeling. Identified and placed reported adverse event/term in appropriate SOC (systems organ classification) and updated current labeling (CANCIDAS, MEFOXIN, NORXOIN, INVANZ, CRIXIVAN, and CUPRIMINE).

Awards of Excellence (2002, 2003, 2004, 2005, 2006, 2007, 2008): Marketing and Leadership Principles Recognized for collaborative effort in MedDRA update, safety update negotiations (QTc prolongation); six filings within limited timelines, EU renewal for Crixivan within very tight timelines, and completed CANCIDAS PLR [Physicians Labeling Rule) update and US pediatric sNDA filing, ROW and EU

Merck & Co., Rahway, NJ
Occupational Health
Clinical Occupational Registered Nurse *1998 –2002*

- *Received Lifesaver Award 1999*

- Special Achievement Award, Merck & Co. & Inc. 1999

ADDITIONAL PROFESSIONAL EXPERIENCE

Robert Wood Johnson University @ RAHWAY, Rahway, NJ **Jul 1977-present**

Emergency Room RN *(ICU/Charge Nurse* ***(currently per Diem)***

- Utilizes the Nursing process to provide emergency health care, to all populations across all age spans. ACLS, PALS, IV and Critical care certified, BLS.
- Conduct assessment and provides patient care in emergent situations.
- Communicates with members of the interdisciplinary team, as appropriate about changes in patient's clinical condition including results of diagnostic studies and symptoms. Is able to respond quickly and accurately to changes in condition or response to treatment.
- Participates in quality and process improvement in the department during all phases from planning to implementing and sustaining efforts.
- Initiates the Admission Assessment, patient history and medication profile within one hour of patient's arrival to the unit.
- Documents on the electronic and paper medical record.
- Assumes a leadership role for groups of patients for assigned length of shift.
- Clinical Excellence Nomination Award – Rahway Hospital, 1993
- Intensive Care experience 1977 to 1982.

Assistant Nurse Manager *Jan 1990 - May 1997*

- Responsible for the organization, functional management, and leadership of department, while containing costs and meeting staff and customer satisfaction.
- Coordinate, supervise, educate, and direct appropriate unit personnel.
- Instrumental in the development, design and application of quality assurance programs, standards of care, as well as Standard Operating procedures.
- Develop, audit and analyze programs for improvement.
- Developed and maintained personnel competency compliance records.
- Developed, designed and implemented customer satisfaction programs–call back system, currently in use.

Somerset Medical Center, Somerset NJ *Nov 2009- Jun 2014*
Registered Nurse/ER ***(per Diem)***

- Utilizes the Nursing process to provide emergency health care, to all populations across all age spans. ACLS, PALS, IV and Critical care certified, BLS.

Middlesex County College, Edison, NJ**/Union County College,** Union, NJ
Faculty adjunct *1991-1992*
Faculty adjunct *1984-1986*
Emergency Medical Technician Instructor

EDUCATION AND LICENSURE

Master's in Public Administration, Emphasis in Healthcare/Health Management, *KEAN UNIVERSITY, 1998*

Bachelors of Science in Nursing (BSN), *FELICIAN COLLEGE, 1985*

Associate of Science in Nursing (ASN), *MIDDLESEX COUNTY COLLEGE, 1977*

Registered Professional Nurse (BSN, MPA) 1978-Present

CERTIFICATIONS

- Licensure as Registered Professional RN
- BLS/PALS/ACLS/IV/Critical Care certified, 1978 to Present

SOCIETY MEMBERSHIPS

- Member, Drug Information Association (DIA) 2002- 2010
- Volunteer Active participant –"Healing the Children", a non-profit, non-partisan volunteer, charitable organization whose principal purpose is to secure/make available free medical treatment for needy children from the United States and abroad. 1995-Present: traveled to El Salvador, Panama and Honduras.
- Emergency Nurses Association Member (ENA), 1984-present
- NJ State Industrial Safety Commission,1988-2008

ACADEMIC AND PROFESSIONAL HONORS

- **Award of Excellence (1999, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2010): Marketing and Leadership Principles Recognized for collaborative effort in MedDRA update, safety update negotiations (QTc prolongation);EU renewal for Crixivan within very tight timelines with 5 requests for supplemental information (RSI) and Completed 1/2008-CANCIDAS PLR and pediatric sNDA filing for US, ROW/EU.**
- American Society of Safety Engineers- Certificate of Recognition as Healthcare Chairperson, 1996

PUBLICATIONS AND PATENTS

- Publication of abbreviated CSR: A Double-Blind, Randomized, Placebo-Controlled, Multicenter, Parallel-Group, Dose-Ranging Study of MK-0633 in Adult Patients with Chronic Asthma.