Angela N. Johnson, PhD

LIFE SCIENCES AND TECHNOLOGY EXECUTIVE

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A life sciences and technology executive with more than 25 years of experience developing technologies for the life sciences.

Developing products that innovate at the edge in some of the most impactful and highly regulated areas, like health tech, fintech, and biotech, is what I do. I have held P&L responsibility, led global organizations of more than 100 people, and led technical, R&D, clinical and scientific, regulatory, and cybersecurity diligence on acquisitions, working with founders, boards, and venture capital (VC) and private equity (PE) investors. I also teach product development and regulatory strategy at Northeastern University, publish, and coach founders, investors, clinicians, scientists, and engineers growing into leadership.

My work covers both sides of bringing a technology to the market. From product design and development and getting the most out of R&D and laboratory teams, to scaling enterprise clinical infrastructure and network security through medical imaging, PACS, and data science to the governance of AI and software. In biotech and medtech where clinical research and data science (HEOR/RWE) are strategic, I have demonstrated success in taking companies from IND and IDE clinical trial filings through Phase 1 to 3 trials to 510(k), PMA, NDA, BLA, and MAA approvals, under GCP, GMP, and the wider GxP quality systems.

25+ YEARS OF EXPERIENCE	100+ PEOPLE LED	40+ COUNTRIES OVERSEEN	60+ PUBLICATIONS AND TALKS

PhD, technical communication. MSE, materials science and engineering · Product Development Expert, RAC and PMP certified · Adjunct Faculty, Northeastern University

AREAS OF EXPERTISE

Health technology and clinical IT

- EHR integration, including Epic
- PACS, DICOM, and imaging core labs
- Laboratory systems and electronic lab notebooks (ELN)
- Clinical trial, real-world evidence (RWE), clinical decision support (CDS), and prescribing platforms
- HIPAA de-identification and data governance
- Hospital IT infrastructure and network security

Clinical research

- IND, IDE, and CTA filings
- Phase 1 to 3 and pivotal device trials
- First-in-human programs
- ICH E6 and ISO 14155 GCP
- Protocols, study reports, and clinical evaluation reports
- Real-world evidence and registries

AI and cybersecurity governance

- AI and software as a medical device (SaMD)
- Predetermined Change Control Plans (PCCP)
- Drift and bias monitoring
- EU AI Act and ISO/IEC 42001
- Section 524B, SBOM, and threat modeling
- Penetration testing, and white-box and black-box red teaming
- ISO 27001, NIST CSF, HITRUST, and SOC 2
- Local small language model (SLM) development and deployment
- NVIDIA and alternative AI hardware installations

Product approvals

- 510(k), De Novo, and PMA
- CE mark under EU MDR and IVDR
- NDA, BLA, and MAA
- 505(b)(2) and ANDA
- Orphan, Fast Track, Breakthrough, RMAT, and PRIME designations
- eCTD submissions and agency meetings
- OTC and OEM products, relabeling, and specification development

Diligence and capital

- Buy-side and sell-side diligence
- Data rooms and investor updates
- Series B, IPO, and asset exit
- Post-merger integration
- P&L ownership
- Market access, reimbursement, HEOR, and CPT coding

Quality systems and audits

- GxP, GCP, and GMP
- ISO 13485, ISO 9001, and 21 CFR Part 11
- FDA BIMO inspections
- MDSAP and Notified Body audits
- Computer system and software validation
- CAPA and audit readiness
- Manufacturing site oversight, and CMO and CDMO selection
- Formulation development support
- IEC 60601 electrical safety testing
- Sterility assurance, including work with the EMA Quality Innovation Group (QIG)
- Biocompatibility (ISO 10993)

Health authorities FDA · EMA · MHRA · Health Canada · PMDA · NMPA · ANVISA

PROFESSIONAL EXPERIENCE

2025 to present
Boston, MA

Senior Vice President, Advisory Services
Avania

Strategic oversight and P&L ownership for the advisory services division, spanning Software as a Medical Device (SaMD) and clinical AI/ML full stack development and CI/CD, regulatory strategy, cybersecurity and penetration testing, R&D engineering and product development, product compliance, market access and reimbursement, medical coding and billing, and AI/SaMD advisory across medical devices, diagnostics, cell and gene therapies, and device-led and drug-led combination products.

- **Regulatory, compliance, and market access leadership.** Leads a team serving more than 450 medtech and biotech customers developing innovative FDA, EU MDR/EMA, and globally regulated medical products, alongside diagnostics innovators, CLIA laboratories, and hospital and academic research partners. Leads reimbursement strategy across CMS and private payers, covering coding, coverage, and payment pathways.
- **Clinical research, approvals, and market access.** Oversees all IND and IDE work, FDA/EMA approvals, and CE marking, together with CPT coding, real-world evidence (RWE), health economics and outcomes research (HEOR), and market access.
- **Clinical AI and imaging.** Directs regulatory and technical strategy for clinical AI/ML and imaging software, including PACS and DICOM integration, federated learning study designs, and FDA Predetermined Change Control Plans (PCCP) that govern how adaptive AI is validated, monitored for drift and bias, and updated after deployment.
- **Health data governance and third-party AI risk.** Oversees de-identification, auditability, API interoperability, and data-sharing and quality agreements across multi-party clinical data environments spanning EHR, PACS, and clinical trial systems, and governs third-party AI and software vendor risk.
- **Technology and engineering leadership.** Oversight of the Global Design Lab with end-to-end medical device cybersecurity capabilities (SBOM management, threat modeling, penetration and fuzz testing, vulnerability assessment against CISA KEV, and Section 524B premarket documentation). Full compliance infrastructure for AAMI TIR57 security risk management. Leads vendor security risk assessments (VSRA) and security documentation aligned to NIST CSF and HICP, HITRUST CSF, and SOC 2 Type II, alongside ISO 13485, ISO 9001, GxP, and CAPA. Additional capabilities include IEC 60601 testing, human factors engineering, and software V&V for cardiovascular, neuromodulation, and digital health technologies.
- **Strategic growth.** Expanding Advisory Services from compliance-focused services to premium technology-enabled strategic advisory. Building specialized practices in PCCP strategy, adaptive algorithm validation, EU AI Act compliance, and digital therapeutics regulatory pathways.
- **Team building.** Establishing a team of senior principals with specialized expertise in AI/SaMD, EU MDR Notified Body processes, and FDA breakthrough device pathways. Driving operational improvements including Salesforce Health Cloud modernization and service delivery optimization.

2023 to 2025
Boston, MA

Senior Managing Director, Global Regulatory and Compliance
Cytiva, a Danaher company

Led global regulatory and compliance staff and technology systems for a top-10 life sciences technology company, overseeing more than 100 professionals serving 40+ manufacturing facilities across product compliance, customer services, and lifecycle development, and the delivery of production compliance cloud software to more than 100,000 users across the Americas, Europe, and APAC.

- **Technology and systems leadership.** Owned enterprise Salesforce (SFDC) and Product Lifecycle Management regulatory compliance architecture for customer contact, high-impact infrastructure supporting quality and lifecycle operations and high-volume customer compliance document requests. Led the software development team for a proprietary data lake and customer-facing API delivering change control, compliance, and CAD engineering integration. Directed AI and software rollout for technical writing and R&D teams, including electronic batch records implementation. Managed business intelligence systems development for global operations. The resulting change control, safety notice, and billing platform served physician-, hospital-, and customer-facing operations in 41 countries and improved efficiency by more than 20 percent.

- **Computer vision AI in precision medicine laboratories.** Led integration and GxP validation of computer-vision detection tooling in hospital-facing GMP precision medicine environments, automating sampling inspection and improving error detection in clinical laboratory reporting.
- **Change governance and AI policy.** Governed high-velocity change control, continuous validation, and cybersecurity across connected clinical and laboratory technologies, and prepared the organization for AI/ML integration, United States and European cybersecurity mandates, and the EU AI Act.
- **Board and investor representation.** Primary C-suite, board, and investor authority for global regulatory strategy (FDA, EMA) and vendor governance.
- **Regulatory filings and designations.** Strategic leadership of customer and product filings with FDA, EMA and European competent authorities, and China NMPA, including IND and CTA submissions, BLA and MAA meetings, RMAT and Breakthrough Therapy designation programs, and Master File strategy. Led regulatory and compliance integration for the 2023 combination of Pall and Cytiva and for nanomedicine and lipid nanoparticle technology acquisitions, under cGMP, ISO 13485, and ISO 10993.
- **Compliance and cybersecurity.** Oversight of medical device regulatory compliance for cybersecurity and organizational systems security. Global product and facility compliance across more than 40 countries. Led the medical device regulatory team (MDR/IVDR, 510(k), global registrations). As head of regulatory affairs within the quality organization, led the team that owned all ISO 13485, ISO 27001, and MDSAP certifications and audits.

2021 to 2023
Boston, MA

Global Head of Regulatory Strategy
Roivant Sciences

Led regulatory due diligence and strategic analysis for health tech and biopharma asset acquisitions, managing financial analysts and regulatory strategy teams supporting in-licensing decisions across Roivant's portfolio of subsidiary companies.

- Buy-side technical, regulatory, and cybersecurity diligence and post-acquisition integration for clinical software and AI platforms, including AI/ML-enabled quality systems, DevOps traceability (Jira to QMS), and interoperability with EHR (including Epic) and PACS, bedside monitoring, smart infusion, and drug-delivery platforms
- Buy-side and sell-side biopharma M&A, including data room operations with Pfizer, Takeda, J&J, Teva, and academic partners
- Part of Roivant's 2021 public listing on Nasdaq (ROIV), completed through its business combination with Montes Archimedes Acquisition Corp.
- Regulatory and market access strategy for clinical-stage products in Phase 1 to 3, with dotted-line oversight of the subsidiaries' global regulatory leads across IND, NDA, BLA, CTA, and MAA strategy and operations, including brepocitinib, batoclimab, namilumab, and the sickle cell gene therapy ARU-1801
- Contributed to the 2022 FDA approval of VTAMA (tapinarof) cream for plaque psoriasis (NDA 215272, Dermavant Sciences), with strategic oversight of accelerated CMC submissions and of topline clinical submissions from the PSOARING 1 and PSOARING 2 Phase 3 trials, and developed the strategy for label expansion and for a planned European marketing authorization application (MAA)
- Led strategy and contracting for regulatory agency interactions, including Pre-IND and Pre-Submission meetings
- Buy-side and sell-side health tech ventures, ranging from AI-driven chemistry synthesis to next-generation compliance cloud software deployed at global production scale
- Financial analysis and regulatory program planning for FDA-regulated therapeutic portfolios
- Supported intake and strategic development of active medical technologies across multiple "vant" subsidiaries
- Data-sharing and clinical technology alliances with hospital networks, academic medical centers, and global biopharma partners, including Sunshine Act and transfer-of-value compliance
- Compliance, audit readiness, and certification across sterile compounding, computational and AI, and chemistry laboratories, in partnership with clinical pharmacy leaders and clinicians
- HIPAA-compliant patient and physician support hubs, medical billing, and market access workflows across a multi-subsidiary portfolio

2019 to 2021
Cambridge, MA

Senior Director and Global Head, Regulatory Affairs

Sigilon Therapeutics, a Flagship Pioneering company

As head of regulatory affairs for Flagship-backed Sigilon Therapeutics, served as strategic and operational lead to stand up agile regulatory compliance and technology operations in a start-up environment, leading to FDA, EMA, and ANVISA designations and IND/CTA filings for a first-in-class genetically engineered triple-combination small-molecule coated cell therapy tissue product, with ISO 13485 companion medical device codevelopment.

- Partnered with the CEO, CFO, and CMO on data rooms and monthly board and investor updates, supporting an $80.3M Series B, a NASDAQ initial public offering (SGTX), and the licensing and eventual exit of implantable delivery and biomaterial assets to Eli Lilly
- Led two INDs and four CTAs in Europe and Brazil for first-in-human cell therapy programs in hemophilia A and lysosomal storage diseases (MPS I and II), with multiple Master File filings and Orphan Drug Designations for two candidates across the United States, Europe, and Brazil
- Led regulatory agency meetings, including INTERACT, Pre-IND, innovation, Scientific Advice, and Committee for Advanced Therapies (CAT) meetings
- Directed compliance, architecture, and end-to-end validation of electronic lab notebooks, PACS-integrated imaging core labs, and connected clinical and GMP quality systems
- Oversaw the regulatory team, eCTD publishing team, and vendor services
- Authored primary IND documents, Orphan Drug Designations (ODD), and PRIME and Fast Track designation requests
- Advised on ISO 10993 and medical device compliance for combination products, cell scaffolding, and cell therapy components
- Oversaw CMO and CDMO selection and oversight and CMC regulatory strategy, with formulation development and laboratory oversight

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2018 to 2019
Raleigh, NC

Director, Regulatory Strategic Development and Market Access

IQVIA

Led the launch of IQVIA MedTech's strategic advisory functions during the M&A integration of Novella Clinical. Drove multimillion-dollar strategic business development in the medtech pipeline with oversight of regulatory and data science teams.

- Built an integrated medtech advisory practice during a critical organizational transformation
- Led a global regulatory team of more than 30 through M&A integration
- Established strategic partnerships driving revenue growth in medical device and diagnostics segments
- Managed regulatory associates, managers, and writers on clinical-stage IND and CTA programs in drug-device combination products, gene and cell therapy, and companion diagnostics
- Developed early- and late-stage filing strategy, including BLA and PMA eCTD preparation, advisory meeting materials, End-of-Phase, Pre-BLA, and Pre-MAA agency meetings, and audit preparation for FDA BIMO inspections and Notified Body audits
- Regulatory strategy for CE mark, 510(k), De Novo, and PMA filings for medical devices and for 505(b)(2) and hybrid applications for drug delivery devices and combination products, with EU MDR and IVDR gap analysis, clinical evaluation reports, and training on ISO 14155, ISO 13485, and ISO 10993
- Worked directly with FDA, EMA, MHRA, ANVISA, PMDA, and other health authorities on trial design and regulatory strategy, and reviewed regulatory and compliance assets and risks in due diligence for venture capital and private equity investors
- Led post-merger IT quality architecture, systems integration, and software validation for operations and proposal automation platforms, enabling global data and trial offerings on the IQVIA MedTech platform
- Directed HEOR, real-world evidence, and public health data science across Phase 1 to 4 programs, including multi-source healthcare data aggregation, GxP and HIPAA-compliant patient registries, and observational outcomes studies
- Principal subject matter expert for regulated healthcare data engineering, covering AI/ML radiology algorithm deployments, EHR (including Epic) and PACS data integrations, HIPAA de-identification pipelines, and QMS and SOP governance

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2017 to 2018
Cincinnati, OH

Associate Director, Regulatory and Scientific Affairs
CTI Clinical

Led early-phase regulatory projects for cell and gene therapy (CGT), small molecule delivery with advanced materials (nanomaterials), and medtech products, including novel oncology products and cell, gene, and tissue engineered therapeutics. Led multidisciplinary project teams in gene, cell, and rare disease therapy products. Served as scientific and regulatory resource for business development, advisory boards, and client engagement across drug development and health economics projects. Led a data science and regulatory team delivering big data analytics, HEOR and real-world evidence registries, and public health studies, and applied R-based clinical and health-economic analyses to support CMS reimbursement, private payer coverage, and FDA approvals.

- Led FDA, EMA, and Health Canada meetings, including Pre-IND and End-of-Phase, and prepared the meeting requests and briefing packages
- Wrote and reviewed IND, CTA, BLA, and MAA submission documents in eCTD format for small molecule and cell and gene therapy products, across immuno-oncology, graft-versus-host disease, islet replacement, neuro-oncology, and neurodegenerative disease
- Developed protocols, clinical study reports, investigator brochures, pediatric investigation plans, Orphan Drug Designations, and RMAT and Breakthrough Therapy designation requests
- Produced ICH and ISO GCP compliant documentation for Phase 1 to 3 trials and pivotal medical device trials, with data management, biostatistics, and clinical operations
- Led the clinical evaluation report and 510(k) writing team, including systematic literature reviews and real-world evidence for cardiac stents, implantable devices, cell scaffolds, and diagnostic imaging

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2013 to 2017
Milwaukee, WI

Senior Manager, Clinical Affairs Operations
GE Healthcare, Global Research Organization

Led a global organization of more than 50 people spanning data science and biostatistics, core lab and PACS systems, clinical operations, field clinical services, and medical and technical writing, responsible for clinical validation of more than 200 medical device studies a year across 41 countries, with direct oversight of teams in the US, EU, and China.

- **Algorithm validation and AI/ML leadership.** Led clinical V&V for synthetically reconstructed MRI (MAGiC), earning first FDA, EU, and China NMPA clearances and the AJNR Lucien Levy Award for the landmark multicenter prospective trial. Directed validation of AI-driven passive magnetic ultrasound needle guidance technology (published in *Regional Anesthesia and Pain Medicine*). Managed clinical testing development for the GE, NFL, and DoD Head Health Initiative, a four-year, $60M collaboration on traumatic brain injury imaging.
- **Clinical trials and regulatory approvals.** Led the clinical trial programs behind FDA IDE, 510(k), De Novo, and PMA submissions and IND, NDA, and BLA filings across MRI, PET/CT, ultrasound, blood pressure monitoring, and EEG and waveform technologies, spanning GE's global imaging and radiotracer portfolio and GE Ventures. Led more than 10 device approvals and served as regulatory lead on multiple NDA and BLA approvals through GE partnerships in oncology, cardiovascular, women's health, and neurodegenerative disease. Led agency meetings with FDA, China NMPA, EMA, and Notified Bodies, and wrote protocols, clinical study reports, and submission documents for 510(k), PMA, NDA, ANDA, and BLA filings, clinical evaluation reports, and China registrations.
- **Enterprise clinical data systems.** Led implementation of the Oracle Health Sciences clinical trial platform. Operationalized QMS and lean improvements that drove cost and time efficiencies across portfolios. Directed development of proprietary operational software for clinical trial acceleration.
- **Hospital partnerships and safety.** Directed hospital trial partnerships, investigator-initiated trials, and clinical safety and root-cause investigations, and served as technical and compliance lead for the neurovascular portfolio.
- **Clinical workflow, human factors, and interoperability.** Partnered with hardware and software engineering on clinical UX and human factors validation, hospital workflow design, and clinical IT system selection and validation. Architected metadata-enabled structured authoring and interoperable DICOM imaging and clinical data pipelines aligned to HITECH, CDISC, and hospital interoperability standards.

2010 to 2013
Shanghai, China

Principal Medical Writer, Electrically Active Products
MedSci Healthcare (Bioon Group 生物谷)

Led global medical and technical documentation teams supporting more than 400 clinical trials across the US, EU, and APAC, specializing in software and electrically active medical devices. Wrote premarket clinical trial protocols, reports, and publications for device and pharmaceutical clients including Zeiss, GE, Merck Sharp & Dohme (MSD), Sanofi-Aventis, and Novo Nordisk Research Center. Authored user requirements specifications, clinical software validation protocols, and regulatory documentation for enterprise healthcare software systems and active medical devices. Wrote submission-ready clinical study reports and clinical modules, and reviewed translations for compliance with ISO 14155, ICH E6 GCP, and China Order No. 5.

2000 to 2010
Wilmington, NC

Senior Project Manager, IT Security
EiS Technologies

Led onsite enterprise IT security, server infrastructure, network architecture, and compliance systems installations and upgrades for hospital systems (HIPAA), universities and colleges, North Carolina state facilities, and DoD-compliant installations, leading field teams in network architecture, server deployment and patching, web server administration, and firewall and security appliance hardening. A hands-on technical foundation spanning hardware installation, system administration, and security architecture, built over a decade in a locally owned technology services firm. Liaised with public health organizations and CROs including PPD and Quintiles. Administered ISO 9001 QMS, 21 CFR Part 11, PCI, HIPAA, and FDA compliance.

2007 to 2008
Wilmington, NC

Director, Manufacturing Technologies
Queensboro.com

Led the digital transformation of a large-scale textile manufacturing operation during the industry transition from silk-screen to digital printing. Owned CAD infrastructure, IT systems, and electronic embroidery technology implementation, with full technical ownership of digital printing and graphics systems across manufacturing operations.

2003 to 2006
Greenville, NC

CAD and Technical Writing Leader
Parrott, Inc.

Designed and implemented enterprise CAD/CAM manufacturing infrastructure, moving legacy paper-based pattern systems to the Lectra digital platform. Built foundational manufacturing technology systems for textile production operations.

ACADEMIC APPOINTMENTS

2021 to present
Boston, MA

Adjunct Faculty
Northeastern University, College of Professional Studies

Faculty member teaching FDA regulatory strategy in the Regulatory Affairs master's program.

2011 to 2013
Jacksonville, NC

Associate Faculty
Coastal Carolina Community College

Taught enterprise web development including custom frontend and backend programming, database integration, and scalable content management system (CMS) deployment for production environments. Also served as continuing education instructor and curriculum designer.

EDUCATION

Lubbock, TX

Doctor of Philosophy (PhD), Technical Communication
Texas Tech University

Concentration in the rhetoric of science and healthcare

Dissertation: *Policy Knowledge in Innovation Ecosystems of Global Biomedical Ventures: Entrepreneurial Communication in Decision-making, Risk-taking, and Competitive Advantage*.

Raleigh, NC

Master of Materials Science and Engineering (MSE)
North Carolina State University

Wilmington, NC

Post-graduate study, Applied Medicinal Chemistry
University of North Carolina Wilmington

Greenville, NC

Bachelor of Fine Arts (BFA), Fine Arts and Communications
East Carolina University

COURSES TAUGHT

Northeastern University, Boston, MA

RGA 6463, Regulatory Strategy Throughout the Lifecycle

Coastal Carolina Community College, Jacksonville, NC

CE 141/142/143, Introductory Graphic Design for Business and Medical Professionals

CE 111, Introduction to Document Design for Medical and Science Professionals

PUBLICATIONS

Book chapters

2026 Parks, A., Butt, N., Farcas, S., & **Johnson, A. N.** (2026). Regulatory strategy for digital therapeutics and artificial intelligence-enabled devices. In *ICLG, Digital Health Laws and Regulations 2026* (Chapter 5). Global Legal Group. https://iclg.com/practice-areas/digital-health-laws-and-regulations

2019 **Johnson, A. N.** (2019). Regulating cell & gene therapies, genetically modified cells and devices in regenerative medicine. In *US Regulatory Affairs Fundamentals* (11th ed.). Regulatory Affairs Professionals Society (RAPS).

2017 **Johnson, A. N.** (2017). Medical device clinical testing and GCPs. In *US Regulatory Affairs Fundamentals* (10th ed.). Regulatory Affairs Professionals Society (RAPS).

Peer-reviewed journal articles and conference abstracts

2026 **Johnson, A. N.** (2026). From indicators to dynamics: Metastability, recurrence, and ignition in a persistent agent's attention stream. *Models of Consciousness 7, Association for Mathematical Consciousness Science*. Copenhagen, October 15, 2026. [Presentation deck]

Butt, N., Chan, D., & **Johnson, A. N.** (2026). Submission-ready or submission-deficient? Cybersecurity documentation and PCCP requirements for AI-enabled devices. *HealthSec*, Boston, MA, June 2, 2026.

Johnson, A. N. (2026). What really happens when a dev vibes with the code? An empirical study on LLM behavioral divergence in response to expressive code comments. *Frontiers in Artificial Intelligence, 9*, 1784973. doi:10.3389/frai.2026.1784973

2023 **Johnson, A. N.**, Fulgoni, A., Wang, L., Racordon-Pape, S., & Almgren, M. (2023). Quantifying challenges to development of generics and biosimilars in non-Hodgkin's lymphoma therapeutics: The future of low-cost alternatives from monoclonal antibodies to CAR-T [Abstract 5148]. *Blood, 142*(Supplement 1). Presented at the 65th American Society of Hematology Annual Meeting, San Diego, CA. https://ash.confex.com/ash/2023/webprogram/Paper187818.html

2021 **Johnson, A. N.** (2021). A look at FDA's gene and cell therapy framework launch in 2020, and its impact on new hemophilia treatments in 2021 and beyond. *Dateline Federation: Emerging Therapies Special Issue, 22*(1), 7. https://www.hemophiliafed.org/dateline/

2020 **Johnson, A. N.** (2020). An ethnographic pilot study of decision-making among non-research physicians. *Molecular Therapy, 24*(No. 7, Supplement 1), 157.

Johnson, A. N. (2020). Public engagement in novel gene therapies for hemophilia and blood disorders: A computational analysis of public sentiments in social media. *Molecular Therapy, 24*(No. 7, Supplement 1), 158.

2019 **Johnson, A. N.** (2019). Determinants of patient response to clinical trial recruitment advertisements in gene therapy: A pilot ethnographic study and trend-over-time simulation model. *Molecular Therapy, 27*(No. 4, Supplement 1), 157.

2018

Qi, W., Davis, H. W., Chu, Z., Vallabhapurapu, S. D., Hussain, N., Franco, R. S., Morris, J. C., **Johnson, A. N.**, & Olowokure, O. O. (2018). Combined effect of gemcitabine (GEM) and sapC-DOPS nanovesicles on pancreatic ductal adenocarcinoma (PDAC) in mice. *Journal of Clinical Oncology, 36*(Supplement). ASCO Annual Meeting Proceedings.

Cruze, C. A., Rixe, O., Morris, J. C., Puduvalli, V. K., Villano, J. L., Wise-Draper, T. M., **Johnson, A. N.**, & Wesolowski, R. (2018). Allometric scaling of preclinical pharmacokinetic and toxicokinetic parameters to predict clinical pharmacokinetics of BXQ-350 saposin C protein-phosphatidylserine nanovesicles. *Journal of Clinical Oncology, 36*(Supplement). ASCO Annual Meeting Proceedings.

Cruze, C. A., Rixe, O., Morris, J. C., Puduvalli, V. K., Villano, J. L., Wise-Draper, T. M., **Johnson, A. N.**, & Wesolowski, R. (2018). Absence of indicators of hypercoagulability and antiphospholipid syndrome in BXQ-350 first-in-human study. *Journal of Clinical Oncology, 36*(Supplement). ASCO Annual Meeting Proceedings.

Rixe, O., Morris, J. C., Puduvalli, V. K., Villano, J. L., Wise-Draper, T. M., Muller, C., **Johnson, A. N.**, Wesolowski, R., & Qi, X. (2018). First-in-human, first-in-class phase 1a study of BXQ-350 for solid tumors and gliomas. *Journal of Clinical Oncology, 36*(Supplement). ASCO Annual Meeting Proceedings.

Johnson, A. N. (2018). Virtual and augmented reality as game-changers in anesthesiology: History, applications, and challenges for clinical virtuality. *Journal of Anesthesia & Intensive Care Medicine, 5*(1), 555652. https://juniperpublishers.com/jaicm/JAICM.MS.ID.555652.php

2017

Hassan, A. E., Sanchez, C., & **Johnson, A. N.** (2017). Endovascular treatment outcomes using the Stroke Triage Education, Procedure Standardization, and Technology (STEPS-T) program. *Interventional Neuroradiology, 24*(1), 51-56. doi:10.1177/1591019917740100, PubMed 29119876

Tanenbaum, L., Tsiouris, A. J., **Johnson, A. N.**, Naidich, T. P., DeLano, M. C., Melhem, E., Quarterman, P., Parameswaran, S. X., Shankaranarayanan, A., Goyen, M., & Field, A. (2017). Synthetic MRI for clinical neuroimaging: Results of the Magnetic Resonance Image Compilation (MAGiC) prospective, multicenter, multireader trial. *American Journal of Neuroradiology, 38*(6), 1103-1110. doi:10.3174/ajnr.A5227, PubMed 28450439. Cover of the issue. Medical illustrations and cover image by A. N. Johnson.

Johnson, A. N., Peiffer, J. S., Halmann, N., Delaney, L., Owen, C. A., & Hersh, J. (2017). Ultrasound-guided needle technique accuracy: Prospective comparison of passive magnetic tracking versus unassisted echogenic needle localization. *Regional Anesthesia and Pain Medicine, 42*(2), 223-232. doi:10.1097/AAP.0000000000000549, PubMed 28079754

Johnson, A. N. (2017). Harmonization of gene therapy regulation. *Regulatory Focus*. Regulatory Affairs Professionals Society.

Johnson, A. N. (2017). Small organizations, big regulatory strategy. *Regulatory Focus*. Regulatory Affairs Professionals Society.

2016

Johnson, A. N., Lauer, C., & Cadogan, C. (2016). How did you get here? Stories of bench research, Bollywood, and stormy epiphanies. *AMWA Journal, 33*(3), 118-119.

Johnson, A. N. (2016). Social norms of "good" design: Interdisciplinary perspectives from a survey of engineers and clinicians in bioengineering. *Proceedings of the 2016 IEEE 38th Annual International Conference of the Engineering in Medicine and Biology Society (EMBC)*, Orlando, FL, 4337-4340. https://ieeexplore.ieee.org/document/7591687/

Johnson, A. N. (2016). Perception and implementation of collaborative documentation technologies among medical physics educators and industry professionals: A current practice survey. *Medical Physics, 43*, 3355. https://doi.org/10.1118/1.4955697

Johnson, A. N. (2016). Accuracy of passive magnetic ultrasound needle guidance in high-fidelity conventional and novel simulated block approach phantoms. *Medical Physics, 43*, 3461. https://doi.org/10.1118/1.4956135

REFEREED PRESENTATIONS

2026

Johnson, A. N. with Ashtor, J., & Muppalla, V. R. (2026, April 5). *AI Agents Are Ready for Healthcare and Medtech. Is it ready for them?* [Panel presentation]. AI Agent Conference, New York, NY.

2025

Johnson, A. N. (2025, June 16). *Regulatory acceleration & innovation: Leveraging new policies for a smarter biopharma go-to-market strategy* [Panel presentation]. BIO International Convention, Boston, MA.

Wang, L., & **Johnson, A. N.** (2025, May). *Strategies and technologies for advanced CMC* [Oral presentation]. International Society for Cell & Gene Therapy (ISCT) Annual Meeting.

2024

Johnson, A. N. (2024, September 18). *Accelerating novel platforms into the clinic: Early experiences with FDA's Advanced Manufacturing Technology (AMT) designation and global perspectives* [Conference presentation]. Regulatory Affairs Professionals Society (RAPS) Convergence, Long Beach, CA.

Nurbo, J., & **Johnson, A. N.** (2024, May). *Comparative interrater analysis of regulatory challenges in recently approved gene therapies for sickle cell disease: Towards a semi-quantitative method for assessing gene therapy regulatory development complexity* [Poster presentation]. American Society of Gene & Cell Therapy (ASGCT) 27th Annual Meeting.

Wang, L., & **Johnson, A. N.** (2024, May). *Systematic analysis of primary field data from biologics therapy regulatory non-approvals: Why aren't we talking about FDA rejections* [Oral presentation]. American Society of Gene & Cell Therapy (ASGCT) 27th Annual Meeting.

Johnson, A. N. (2024, May). *Comparative analysis of sterile grade filters in adeno-associated virus (AAV) manufacturing: Accelerating first-in-human AAV therapeutic production with quality by design principles* [Oral presentation]. American Society of Gene & Cell Therapy (ASGCT) 27th Annual Meeting.

Abate, E., White, G., Kassim, S., Sivlotti, M., Westberg, M., & **Johnson, A. N.** (2024, May). *Deliver what's next: Fueling the future of autologous CAR-T therapy* [Conference presentation]. International Society for Cell & Gene Therapy (ISCT) Annual Meeting.

2021

Johnson, A. N., & Zahora, J. (2021, November). *Working through contract research organization (CRO) issues to stay in control of your study* [Panel presentation]. Outsourcing Clinical Trials New England.

Johnson, A. N. (2021, May). *Ethnographic social world and actor-network analysis of the gene therapy commercialization landscape* [Poster presentation]. American Society of Gene & Cell Therapy (ASGCT) 24th Annual Meeting.

Johnson, A. N. (2021, March). *Optimizing regulatory strategy for gene therapies: Current trends, guidance and industry milestones* [Conference presentation]. Gene Therapy for Rare Blood Disorders Conference, Boston, MA.

2020

Johnson, A. N. (2020, June). *Drug-device combination treatments and diagnostics* [Roundtable session]. Proventa International CMC Regulatory Affairs Summit.

Johnson, A. N. (2020, May). *Public engagement in novel gene therapies for hemophilia and blood disorders: A computational analysis of public sentiments in social media* [Poster presentation]. American Society of Gene & Cell Therapy (ASGCT) 23rd Annual Meeting.

Johnson, A. N. (2020, May). *Prescribing gene therapy: An ethnographic pilot study of decision-making among non-research physicians* [Poster presentation]. American Society of Gene & Cell Therapy (ASGCT) 23rd Annual Meeting.

Johnson, A. N. (2020, March). *Gaining insights into a successful hemophilia gene therapy trial* [Conference presentation]. Gene Therapy for Rare Blood Disorders Conference, Boston, MA.

Johnson, A. N. (2020, March). *Strategic gene therapy product platforms and partnerships: From codevelopment to companion products* [Workshop]. Gene Therapy for Rare Blood Disorders Conference, Boston, MA.

2019

Johnson, A. N. (2019). *Accelerating innovative device strategy: From modernizing the 510(k) to improving the de novo* [Conference presentation]. Regulatory Affairs Professionals Society (RAPS) Convergence, Philadelphia, PA.

Johnson, A. N. (2019). *Determinants of patient response to clinical trial recruitment advertisements in gene therapy: A pilot ethnographic study and trend-over-time simulation model* [Conference presentation]. American Society of Gene & Cell Therapy (ASGCT) Annual Meeting, Washington, DC.

Johnson, A. N. (2019). *Introducing agile in regulated industries: Leading agile in MedTech* [Conference presentation]. TriAgile, Raleigh, NC.

2018

Johnson, A. N. (2018). *If you can write a grant, you can write a pitch deck* [Conference presentation]. American Medical Writers Association (AMWA) Annual Conference.

Johnson, A. N. (2018). *Leaping from desk to podium: Essential presentation skills for medical writers* [Conference presentation]. American Medical Writers Association (AMWA) Annual Conference.

Johnson, A. N. (2018). *Human gene editing and advanced therapies: How will FDA, EMA, and gene therapy mix?* [Conference presentation]. Regulatory Affairs Professionals Society (RAPS) Convergence, Vancouver, BC.

Johnson, A. N. (2018). *The gap between clinician-led cell therapy evidence and marketed products: A quasi-experimental comparative pilot study of young venture clinical development* [Poster presentation]. American Society of Gene & Cell Therapy (ASGCT) Annual Conference.

Rixe, O., Morris, J. C., Puduvalli, V. K., Villano, J. L., Wise-Draper, T. M., Muller, C., **Johnson, A. N.**, Wesolowski, R., & Qi, X. (2018). *First-in-human, first-in-class phase 1a study of BXQ-350 for solid tumors and gliomas* [Poster discussion panel]. American Society of Clinical Oncology (ASCO) Annual Meeting.

2017

Johnson, A. N. (2017). *Explore the global medical writing movement and emerging career growth opportunities* [Conference presentation]. CBI Medical Writing Summit, Philadelphia, PA.

Martin, R., & **Johnson, A. N.** (2017). *From additive to algorithm* [Medical device session]. Regulatory Affairs Professionals Society (RAPS) Convergence, Washington, DC.

Johnson, A. N. (2017). *Mentoring and growing medical writing teams* [Roundtable panel]. American Medical Writers Association (AMWA) Annual Conference.

Wilson, E., Hebert, K. A., Turco, T. J., **Johnson, A. N.**, & Hersh, J. K. (2017). *Direct and indirect costs comparison of cardiac diagnostic pathway in coronary artery disease: CCTA as the optimal gateway to ICA* [Abstract]. American College of Cardiology (ACC) Annual Meeting, Washington, DC.

2016

Johnson, A. N., & Murphy, S. (2016). *Usability and interoperability of medical device software* [Conference presentation]. Regulatory Affairs Professionals Society (RAPS) Convergence, San Jose, CA.

Johnson, A. N. (2016). *Collaborative writing toolkit: Results of a survey of American medical and technical writers in health care* [Poster presentation]. American Medical Writers Association (AMWA) Annual Conference.

Johnson, A. N. (2016). *It's time for medical writers to get big and dirty: Writing opportunities in data, biometrics, and technology* [Conference presentation]. American Medical Writers Association (AMWA) Annual Conference.

Johnson, A. N., Cadogan, C., & Lauer, C. (2016). *Writing under fire: Skills and opportunities for writing in a crisis* [Conference presentation]. American Medical Writers Association (AMWA) Annual Conference.

Johnson, A. N., & Bippes, B. (2016). *Evidence and power: Empowering research through mixed-methods in resource-limited, feasibility, and pilot studies* [Conference presentation]. American Society for Bioethics and Humanities (ASBH) Annual Conference.

Johnson, A. N., & Bippes, B. (2016). *Picking the "good" drugs: Empirical evidence for the role of physician morality in prescribing new medications* [Pharmacy ethics session]. American Society for Bioethics and Humanities (ASBH) Annual Conference.

Johnson, A. N. (2016). *Accuracy of passive magnetic ultrasound needle guidance in high-fidelity conventional and novel simulated block approach phantoms* [Conference presentation]. American Association of Physicists in Medicine (AAPM) Annual Conference.

Johnson, A. N. (2016). *Social norms of "good" design: Interdisciplinary perspectives from a survey of engineers and clinicians in bioengineering* [Conference presentation]. IEEE Engineering in Medicine and Biology Society (IEEE/EMBS) Annual Conference, Orlando, FL.

2015

Johnson, A. N. (2015). *Standards from the start: A practical perspective on strategic use of CDISC Protocol Implementation Model 1.0* [Conference presentation]. CDISC International Interchange.

Johnson, A. N. (2015). *Traumatic brain injury patient narratives in social media* [Conference presentation]. American Society for Bioethics and Humanities (ASBH) Annual Conference.

Johnson, A. N. (2015). *Social media and patient communication: Writing and research strategies to increase online impact* [Poster and oral presentation]. American Medical Writers Association (AMWA) Annual Conference.

Cadogan, C., **Johnson, A. N.**, & Lauer, C. (2015). *Transitioning into medical writing for diverse professionals* [Poster presentation]. American Medical Writers Association (AMWA) Annual Conference.

2014

Johnson, A. N. (2014). *How to: A practical introduction to the language and rhetoric of medical device software* [Poster and oral presentation]. American Medical Writers Association (AMWA) Annual Conference.

Johnson, A. N., Cadogan, C., & Wang, X. (2014). *From R&D to clinical trials: Medical writing strategies for global teams* [Poster and oral presentation]. American Medical Writers Association (AMWA) Annual Conference.

2013 **Johnson, A. N.** (2013). *Building and growing medical writing websites using open source content management systems (CMS)* [Workshop]. American Medical Writers Association (AMWA) Annual Conference.

EDITORIAL EXPERIENCE

2012 *Medicine* (Wolters Kluwer Health). Academic Editor and Manuscript Reviewer. 2012 to present.

2017 *Molecular Therapy* (Cell Press / ASGCT). Reviewer. 2017 to present.

2012 *Neurology* (AAN). Reviewer. 2012 to present.

MEDIA AND PRESS

2025 Cited in: Philippidis, A. (2025). "In-region, for region": Cytiva builds out $1.6B in global expansion projects. *GEN Edge, 7*(1), 452-458. https://doi.org/10.1089/genedge.7.1.084

Quoted in: Philippidis, A. (2025, June). Compliance head: "We need to keep that big picture" on drug development amid regulatory changes. *GEN Edge*. [Coverage of BIO International Convention panel presentation.]

2024 Panelist in: **Johnson, A. N.**, Stenklo, K., Tuvesson, O., & Barberio, J. (2024, September 24). *Navigating the regulatory and manufacturing realities of mRNA therapeutic development* [Webinar]. *Genetic Engineering & Biotechnology News (GEN)*. https://www.genengnews.com/multimedia/navigating-the-regulatory-and-manufacturing-realities-of-mrna-therapeutic-development/

PROFESSIONAL SERVICE

2026 Boston Community Ambassador, Healthcare & Medical, Anthropic, 2026 to present

2025 Co-Chair, Chemistry, Manufacturing, and Controls (CMC) Committee, American Society of Gene & Cell Therapy (ASGCT), 2025

2024 CMC Manufacturing Panel Moderator, American Society of Gene & Cell Therapy (ASGCT), 2024

2018 Government Relations Committee Member, American Society of Gene & Cell Therapy (ASGCT), 2018 to 2022

2007 Board Member, Biotech Mentor, 2007 to present

2018 Contributing Member, American Society for Quality (ASQ), 2018 to 2020

2015 Educational Board Member, Association of Clinical Research Professionals (ACRP), 2015 to 2016

2016 Historical Board Member, American Association of Physicists in Medicine (AAPM), 2016 to 2017

2015 Working Group Member, ISO/IEEE 11073 Personal Health Data (PHD) Interoperability Standards, 2015 to 2016

2014 Medical Advisory Board Writer, GE-NFL Head Health Initiative, 2014 to 2016

2015 Co-Chair, Educational Committee (Greater Chicago Area), Association of Clinical Research Professionals (ACRP), 2015 to 2016

Synoptics Wordscape Project, Texas Tech University Humanities Center, 2015

2013 Online Resources/Web Development Committee, American Medical Writers Association (AMWA), 2013 to 2015

CERTIFICATIONS

Active, 2015 to present — Regulatory Affairs Certification (RAC-US)
Regulatory Affairs Professionals Society (RAPS)

Active, 2020 to present — Certified Pharmaceutical GMP Professional (CPGP)
American Society for Quality (ASQ)

Active, 2012 to present — Project Management Professional (PMP)
Project Management Institute (PMI)

2024 — Leading with Finance
Harvard Business School

2016 — Design and Interpretation of Clinical Trials
Johns Hopkins University

	Six Sigma Green Belt GE Crotonville, Healthcare Institute (HCI)
	Operations Management University of Illinois Urbana-Champaign
2015	Private Equity and Venture Capital Management Università Bocconi, Italy
2013	High Speed Project Management University of Wisconsin-Madison
2008	Project Management Certificate Cape Fear Community College

FUNDING AND AWARDS

2017	Lucien Levy Award, Best Original Research Article *American Journal of Neuroradiology* (AJNR)
2016	Regulatory Affairs Convergence Faculty Speaker Honorarium (grant awarded) Regulatory Affairs Professionals Society (RAPS), San Jose, CA
	GE Health Analytics Hackathon, 1st Place, Cardiac CAD in R (grant awarded) GE Healthcare Science and Technology Week
	GE makerPOSSIBLE Laser Cut Bridge Challenge ("The Art of Biomechanics"), 1st Place, Artistry (grant awarded) GE Healthcare Science and Technology Week
	Employee Tuition Fellowship (4-year grant awarded) GE Healthcare
	Ralph W. Brauer Fellowship in NMR Spectroscopy and Proteomics (1-year grant awarded) University of North Carolina Wilmington
	East Carolina Academic Merit Fellow (scholarship grant awarded) East Carolina University

COMMUNITY AND NONPROFIT

2024	The Real Cat Labs (2024 to present). Board member. Nonprofit 501(c)(3) for furthering education in human-AI interactions and machine cognition research on open, community-focused models. Independent red teaming and evaluation of AI models. therealcat.ai
2016	Insight! Milwaukee (2016 to 2018). Volunteer Health Career Coach, K-12.
2015	Jubilant Kids Foundation of Kenya (2015 to 2016). Volunteer Fundraising Director.
2013	GE-United Way Charity Drive, Milwaukee, WI (2013 to 2016). Volunteer Community Event Coordinator.
2011	Volunteer ASVAB Tutor, Mathematics/Physics, Community Services, Wilmington, NC (2011 to 2012).
2009	Tileston Health Clinic, Wilmington, NC (2009 to 2011). Patient advocate, prepared chronic medication assistance applications for low-income patients.