

# SABUNE JOANE WINKLER, JD

## CHIEF OPERATING OFFICER | N'ZUMA

Global Operations • Regulatory Strategy • Organizational Infrastructure • Cross-Border Growth

### EXECUTIVE PROFILE

Operations-minded legal executive, regulatory architect, and entrepreneur with 30 years of experience transforming complex requirements into scalable systems, partnerships, and growth strategies. Proven record of building programs from inception, aligning stakeholders across large institutional networks, negotiating mission-critical agreements, and leading national and international initiatives through implementation. Brings N'Zuma a distinctive combination of operating discipline, governance expertise, cross-border market development, and hands-on venture leadership across U.S., African, and global environments.

**Enterprise Operations:** Builds operating frameworks, policies, workflows, and accountability mechanisms that move strategy into execution.

**Stakeholder Alignment:** Creates consensus across executives, institutions, regulators, researchers, and external partners.

**Cross-Border Execution:** Translates legal, regulatory, and market complexity into practical operating strategies across jurisdictions.

**Growth Enablement:** Structures partnerships, agreements, and compliant pathways that support investment, innovation, and expansion.

### CORE EXECUTIVE CAPABILITIES

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|------------------------------------|------------------------------------------|----------------------------------------|
| Operational Strategy & Execution   | Organizational Design & Program Building | Governance, Risk & Compliance          |
| Cross-Functional Team Leadership   | Strategic Partnerships & Negotiations    | International Market Development       |
| Policy & Process Harmonization     | Regulatory and Government Affairs        | Change Management & Consensus Building |
| Research and Innovation Operations | Data Privacy & Security Strategy         | Entrepreneurial Venture Development    |

### SELECTED LEADERSHIP EXPERIENCE

#### SAPHAN PONT LAW PARTNERS | Principal & Founder

*Boutique legal and regulatory advisory firm serving life sciences and emerging-therapy organizations.*

- Direct firm operations and advise companies at the forefront of bench-to-bedside research and development, converting complex regulatory, privacy, contracting, and governance requirements into executable business strategies.
- Draft, review, and negotiate high volumes of clinical trial, confidentiality, master service, vendor, consulting, data-sharing, sponsored research, CRO, and technology-transfer agreements.
- Develop operating approaches for compliant data use and transfer under U.S. FDA, EMA, HIPAA, and GDPR frameworks, helping organizations anticipate shifting federal, state, and international requirements.
- Integrate research ethics and privacy-by-design into clinical development and access models for novel therapies, including psychedelic therapeutics.

#### HARVARD MEDICAL SCHOOL | Founder & Director, Regulatory Foundations, Ethics & Law Program

*Program and network leadership across 22 Harvard-affiliated hospitals and research institutes.*

- Established and directed a cross-institutional program that harmonized policies and operating practices across 22 Harvard-affiliated organizations.
- Negotiated landmark data-sharing, IRB, IACUC, IBC, and laboratory agreements, removing long-standing barriers and accelerating multi-site research collaboration.
- Built consensus among legal, research, ethics, compliance, and executive stakeholders and translated institutional priorities into sustainable governance infrastructure.

## HARVARD-AFFILIATED HOSPITALS & RESEARCH INSTITUTES | Attorney

*Massachusetts General Hospital, Brigham and Women's Hospital, Dana-Farber Cancer Institute, and Beth Israel Lahey Health.*

- Advised leading academic medical centers on complex research, operational, contracting, and regulatory matters in high-stakes clinical and scientific environments.

## U.S. NATIONAL INSTITUTES OF HEALTH COLLABORATION | National Initiative Leader

*SMART IRB national reliance initiative and electronic platform.*

- Assembled and managed a 19-member U.S. ambassador team and enrolled more than 100 leading research institutions in a new national collaboration model.
- Delivered the first national IRB reliance agreement and supporting electronic platform; the framework became a U.S. standard for multisite clinical trials and has been adopted by more than 1,000 institutions.
- Served as a principal investigator and researcher on federally funded projects, directing deliverables and stakeholder engagement across complex institutional environments.

## GLOBAL, GOVERNMENT & MARKET-BUILDING LEADERSHIP

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### DEMOCRATIC REPUBLIC OF THE CONGO | Health, Life Sciences & Market Development Advisor

- Advises on health initiatives, including vaccine programs and development of a life sciences market positioned to attract international investment.
- Works to develop a regulated iboga market modeled on Gabon's framework, helping establish the governance and operating foundation for an emerging industry.
- Connects public-sector priorities, international standards, investment considerations, and practical implementation requirements in a complex growth market.

### LIBERIA NATIONAL RESEARCH ETHICS BOARD | Advisor

- Provides strategic counsel on national research ethics governance and the operational infrastructure required to protect participants and support ethical, internationally compliant clinical research.
- Supports development and implementation of practical policies, procedures, oversight models, and cross-institution collaboration mechanisms.

## ENTREPRENEURIAL & COMMERCIAL VENTURES

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### SALT LARDER | Entrepreneur / Operator

*Circular-economy gourmet-salt venture that upcycles agricultural by-products.*

- Applies hands-on commercial leadership to sustainable product development, operations, and locally rooted value creation.

### WHISKY & CIGAR LIBRARY — KINSHASA | Founder / Venture Developer

*Forthcoming hospitality concept in the Democratic Republic of the Congo.*

- Developing an in-market commercial venture that reflects practical experience with concept formation, local execution, and cross-border entrepreneurship.

## THOUGHT LEADERSHIP & PROFESSIONAL IMPACT

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- Delivered hundreds of keynotes, presentations, and posters, including invited addresses at the National Institutes of Health and leading bioscience, research, ethics, and security forums.
- Published in the American Journal of Bioethics, Clinical & Translational Science, IRB: Ethics & Human Research, and Nursing Ethics, shaping practice in community-engaged research, social-media recruitment, and distributed regulatory support.
- Senior author of widely adopted guidance translated into 11 languages and downloaded more than 100,000 times.
- Founding member of the Psychedelic Bar Association; leads the Available Legal Frameworks subcommittee within its Psilocybin Education Initiative and mentors emerging investigators and entrepreneurs.

## RECOGNITION

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- NIH Health Improvement Institute Award for Excellence in Human Research Protection
- Harvard Medical School Daniel Federman Award for Institutional Service
- Sharon P. Clayborne Diversity Award for advancing equity and inclusion

## EDUCATION, ADMISSION & AFFILIATIONS

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| <b>Juris Doctor</b>               | Northeastern University School of Law           |
| <b>Bachelor of Arts</b>           | Bates College                                   |
| <b>Bar Admission / Membership</b> | Massachusetts • American Health Law Association |