



Vorpall Technologies K.K.

 **BioJapan 2016**
Booth No. B-12

Vorpall is the premier pathway into Japan for overseas healthcare innovators. We enable innovators to enter Japan on their own, delivering expert service solutions in clinical, regulatory, reimbursement, quality & safety, logistics and market development. Vorpall is also developing specialty pharma portfolios contributing to the advancement of three therapeutic areas: CNS, GI and OB/GYN.

Greeting



Robert E. Claar
President & CEO

Rob Claar co-founded Vorpall Technologies in 2013 to help create solutions for the drug, device and diagnostics lag and become the premier pathway into Japan for healthcare innovations.

Vorpall is a full-service virtual subsidiary, enabling overseas healthcare innovators to enter Japan on their own terms with transparency, confidence and optionality. Vorpall delivers expert solutions in clinical development, regulatory affairs, reimbursement, quality and safety management, logistics and market development.



Prior to Vorpall, Rob founded Junicon K.K., a healthcare market research and strategy consulting firm. Junicon now has a global reach with offices in the US and Europe and strong affiliations in all major markets.

Rob has over 25 years' experience in healthcare innovation management, opportunity assessment, strategy development and implementation. He is passionate about developing innovative solutions for access to Japan's healthcare market.

Contact

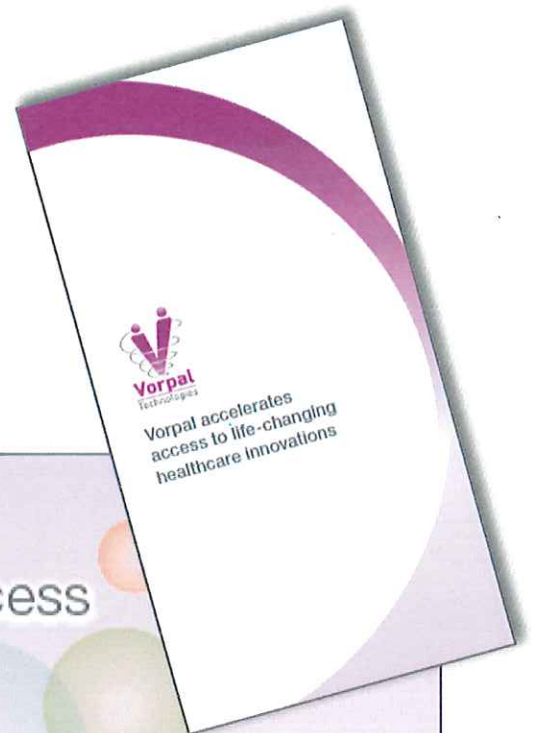
Vorpall Technologies K.K.

Akasaka Garden City, 4-15-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan

 +81 (3) 5544-8340  info@vorpalltechnologies.com

www.vorpalltechnologies.com

Vorpal Technologies K.K. Consulting Service Menu



End-to-end Solutions for Success in Japan's Healthcare Market

Strategy Partnering Execution

Innovation Research & Development

- Joint Development with Clinicians
- Intellectual Property Strategy
- Technology Transfer
- Biomedical Design
- Prototype Development
- Usability Confirmation
- Regulatory Compliance Confirmation

Opportunity Validation

- Patient Population Definition
- KOL Identification & Influence Mapping
- Treatment Landscape Clarification
- Product Evaluation
- Pricing Assessment
- Opportunity Sizing

Clinical Development

- Clinical Trial Design
- In-Country Clinical Caretaker (ICCC) Services
- KOL Engagement & Site Selection
- Clinical Operations & CRO Management
- GCP Compliance Assessments
- Post-Marketing Surveillance (PMS)
- Clinical Research Support

Regulatory Development

- Regulatory Strategy Formulation
- PMDA & MHLW Engagement
- KOL & Medical Society Engagement
- High Medical Needs & HBD Program Listing
- Orphan Drug / Device Designation
- Regulatory File Submission
- Q&A to Approval

Market Access

- Reimbursement Strategy Formulation
- Medical Society Engagement
- Patient Group Engagement
- Treatment Guideline Influencing
- MHLW Engagement
- HTA & Health Economic Analysis
- Reimbursement Application Submission
- Q&A to Acceptance

Quality & Operations

- QMS Development & Maintenance
- Designated Marketing Authorization Holder (D-MAH) Services
- Importation & Market Release
- Labeling & Repackaging
- Warehousing & Logistics
- Vigilance Management & Reporting

Commercial Development

- Marketing & Business Strategy Development
- KOL & Rising KOL Engagement
- Advisory Board Establishment
- Congress Strategy & Implementation
- Clinical Education Program Development
- Clinical Research & Publication Support
- Distribution Partner Selection & Engagement
- Business Incubation & Acceleration
- Sales & Distribution



Vision

Vorpai accelerates access to life-changing healthcare innovations

Mission

- Vorpai enables companies to enter Japan on their own terms with transparency, confidence and optionality
- Vorpai partners with healthcare innovators as a full-service virtual subsidiary, delivering expertise in clinical development, regulatory affairs, quality and safety management, logistics and market development
- Vorpai develops specialty pharma and medical device portfolios for our own commercial operations in Japan, contributing to the advancement of three therapeutic areas: women's health, CNS and GI

5 Values

■ Creativity

Vorpai encourages creative thinking at all levels of our organization. We have the courage to take on new challenges, empowered by our experience, ideas, network, colleagues and opportunities. Vorpai is dedicated to pioneering new strategies and business solutions to enable expanded access to healthcare innovations that benefit patients, families, caregivers and healthcare professionals.

■ Integrity

Vorpai conducts itself with transparency in interactions with clients, business partners, team members and government authorities. We emphasize accountability, trust and compliance at all levels of our organization.

■ Respect

Vorpai has a collaborative working environment based on personal accountability, open communication and respect. Vorpai's aspiration is to create a high performance and friendly environment that enables team members to reach their personal as well as professional goals.

■ Partnership

Vorpai values collaborative relationships among all internal and external stakeholders. Our partnerships are based on common interests and mutual respect.

■ Gratitude

Vorpai feels and demonstrates gratitude for our opportunities, our partners and the environments in which we operate.