

**THE OWNER:** Vips Halkjaer-Knudsen has **more than 30 years experience** in the chemical and biological field, and she has been in the consulting business since 2006.

She is a subject matter expert and has worked as a lead and a team member in groups, as well as on her own, flying solo.

**20+ Years as a Manager and Director:** Vips has, throughout her career, overseen personnel from high performance academic R&D teams, technical staff in GMP QA/QC laboratories, large scale GMP production employees to blue collar service and logistic teams.

**10 Years and Counting:** ...as a technical subject matter expert. After half a life holding the reins as director and facility owner, she decided to change career path, relocated to the other end of the world, joined a team of technical subject matter experts, expanded her reach, and started working with international governments, partners, organizations, companies, scientists and technicians within the worldwide biorisk management field.

**Project Management:** Real life experience from a vast number of building projects has given Vips solid hands-on expertise in project management. Over time she has developed and fine-tuned a comprehensive toolbox of project management tools that are applicable in many different industrial settings.

**GMP Documentation & SOP's:** Vips has many years of GMP experience and has prepared for and passed several FDA GMP inspections. In her years at SSI, there was not a week that did not include the generation of relevant documents for inspections, risk assessments, SOP's and in-house documentation.

**Facility Design:** She has lead design and validation teams, overseen pre-design & programming, detailed design, bidding, construction and commissioning phases on multiple projects, both on site and while being on the other side of the globe. She is a scientist – not architect or engineer.

**Operation & Maintenance:** The job is not done when the new building is handed over, the fun has just started. Vips has, over the years, had her hands deep down in the start-up of facilities and development of operation and maintenance programs.

**Guideline implementation:** ISO 35001, 17025; CWA 15793/16335/16593 and GAPIII, she has done them all.

**URS' and more:** You cannot be involved in more than 6 animal and large scale GMP facility constructions and refurbishment projects and not become skilled in tenders, procurement specifications, user requirement specifications. DQ, IQ, OQ and PQ protocols and reports, evaluation and selection of A&E companies, consultants and contractors.

**Polio:** Vips is serving as a SME for WHO in the Containment Advisory Group (CAG) for Polio eradication. The CAG addresses questions and challenges regarding the worldwide Polio containment implementation.

**Trainer, Instructor & Author:** Vips has more than 20 years experience as a speaker/trainer/instructor and workshop facilitator. She has given more than 150 professional talks at conferences all over the world, taught even more half and full day courses in the “hard” as well as the “soft” topics that are mentioned on her web site. In her spare-time she reviews and edits guidelines, publishes papers and book chapters.



**Vipsit<sup>LLC</sup>** supports A&E Companies, Private Institutions and Governments in the challenging Chemical / Biological / High-Containment field. We plan, lead, develop, review, launch, execute, teach, support or assist - depending on your needs

Assisting during peak loads

We strive to be a credible and reliable resource that can be called forward when needed and stay out of sight in between

Safe Products, Safe Laboratories, Safe Environment, Safe Project Managers ... Safer World

**MISSION: Keep people, animals, environment – and project managers safe**

**VISION: Inspire and facilitate timely due diligence, excellence and success**

We meet you where you are, and we create the systems you need but have not yet had time to build.

We currently serve in several think tanks and advisory boards where we develop new strategies and sustainable approaches.

Vipsit provides support and Subject Matter Expertise (SME) in areas from biological and chemical risk management, high-containment lab-design, facility operation and maintenance to incident management and response.

We perform multidimensional impact- and risk assessment analyses from a product-, GMP-, chemical- and biological, environment-, workers health and safety-, emergency preparedness-, AND animal welfare point of view.

We create protocols for compliances up against guidelines and standards and we train your staff and mentor your BSO's as needed. We are ready to walk our talk with you and make sure your staff reach the desired endpoint. When we leave you, they are ready to meet your inspectors.

We have special focus on soon to be eradicated diseases like Rinderpest and Polio, and emerging diseases like Ebola and COVID-19.

**WHAT:** Vipsit LLC was founded by Dr. Vibeke Halkjaer-Knudsen in 2006 as a small business focused on high containment laboratories from the early design fact-finding phase to final commissioning, training of staff and development of policies, plans and procedures.

**CLIENTS:** We work with architects and engineering (A&E) design companies, lab-planners, project managers and facility owners, safety professionals, equipment suppliers, international organizations, maintenance engineers, scientists, technicians and support staff where additional risk management strengths, skill-sets and resources are needed.

We work with big industry, laboratories, hospitals, schools and universities. We work in the areas where things suddenly can get out of control, infectious agents and toxic chemicals can harm, where spills occur, and exposure can happen.

We work with early career professionals whom we coach and mentor and help get traction in the field. We assist more seasoned career professionals with shortcuts to templates and tools. We step in and lift on any project that needs extra resources for a limited time. And we come to assistance if your project derails. We have been there, been them all, we remember how it was, and we believe we can bring value to your current challenges and situation.

**TEAM:** Vips and her hand-selected team of subject matter experts (SME's) aim for timely due diligence, lay the groundwork for successful project execution and deliver high value services for our clientele. We are a team of SME's serving under the Vipsit umbrella. We are all independent consultants. Sometimes we lift together and sometimes we work alone on individual projects. If you decide to involve us in your project, Vips will serve you herself, or if it is a bigger contract, suggest a team of SME's. You will have a chance to accept or decline the team composition.

***We meet your needs depending on where you are in the process.***

- Initial thoughts, considering how to initiate a project? (fact-finding and user interviews, design, new construction, refurbishment, infill, brownfield, greenfield).
- How to close out a project? (commissioning, validation, operational readiness, set up of maintenance systems and training of staff).
- Or how to rescue a derailed project?

We have a strategic approach when we engage. We identify the critical path and the potential roadblocks, develop tiered plans around those roadblocks, and always have a plan B in mind.

We listen before we talk. We recognize that all costumers, projects and challenges are unique, there is no "one size fits all" approach and that cookie cutters are for baking, not for containment laboratories.

**HOW:** We can do the entire task/project for you, and close out with a final deliverable, or we can work with your team, kick them off and check in from time to time, supporting them as they learn. It depends on whether your company/team have the time and resources to lift yourself, or you are over tasked already and short of time and staff.

We can work remotely over ZOOM, WebEx, Skype, Teams, E-mail, WhatsApp, Viber, Sharepoint sites, Drop-box or any type of platform you are comfortable with. We will interact with you in your typical work hours, even if that is in the middle of our night, and we can under certain circumstances travel to your site and work from there for a shorter time.

**PAST PROJECTS – KEYWORDS:** Animal facilities, Accident/incident/near-misses/close-catches systems, BOD, Biological agents, BRM implementation, Biorisk manuals, Biosafety, Biosecurity, Chemistry, CIP, Cleaning validation, Commissioning, Communication plans, CONOPS, Contract Specifications Review & Analysis, CWA 15793 & CWA 16393, Data Analytics, Decontamination, 30%-60%-90% Design reviews, Diagnostic laboratories, DQ, Equipment, Eradicated diseases, Facility assessments, Facility design, Fermentors, GMO's, GMP production, HEPA filters, High containment, HVAC systems, Impact assessments, Instructional Design, ISO standards, IQ, Kast Hydrology, Kill systems, Laboratories, Large scale productions, Media systems, Metrics, Mixed methods Study Development & Analysis, O&M plans, Operational readiness, OQ, Performance indicators, Pharmaceutical plants, Pilot plants, PQ, Project Management, Qualification, Qualitative Data Analysis, Quantitative Data Analysis, Regulatory compliance, Research laboratories, Reviews, Risk assessments, Room decontamination, Single Use Systems and Equipment, SIP, SOP's, Start-up Testing, Sustainability, Systems Operational Testing, TABLEAUX, Training, User requirement specifications (URS), Utility systems, Vaccines, Validation, Waste

**CONFIDENTIALITY:** We serve many types of clients and we sign NDA's and confidentiality agreements. Some of our contracts are associated with rescue missions and other more sensitive tasks. All our clients will be contacted in advance, and it will be their choice, and theirs alone, if we can disclose their identity for a reference statement or not.

**CONFLICT OF INTEREST:** If your project in any way will conflict with our other work or current projects, we will let you know immediately, and point you in the direction of someone else who can assist you.

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