INCONSULT GmbH

Company Profile

- Location: Duisburg

- Employees: 65+

- More than 20 years experience in Document-, Quality- & Information-Management Systems

- More than 750 major industry projects

- Certified according to DIN EN ISO 9001 / 2015
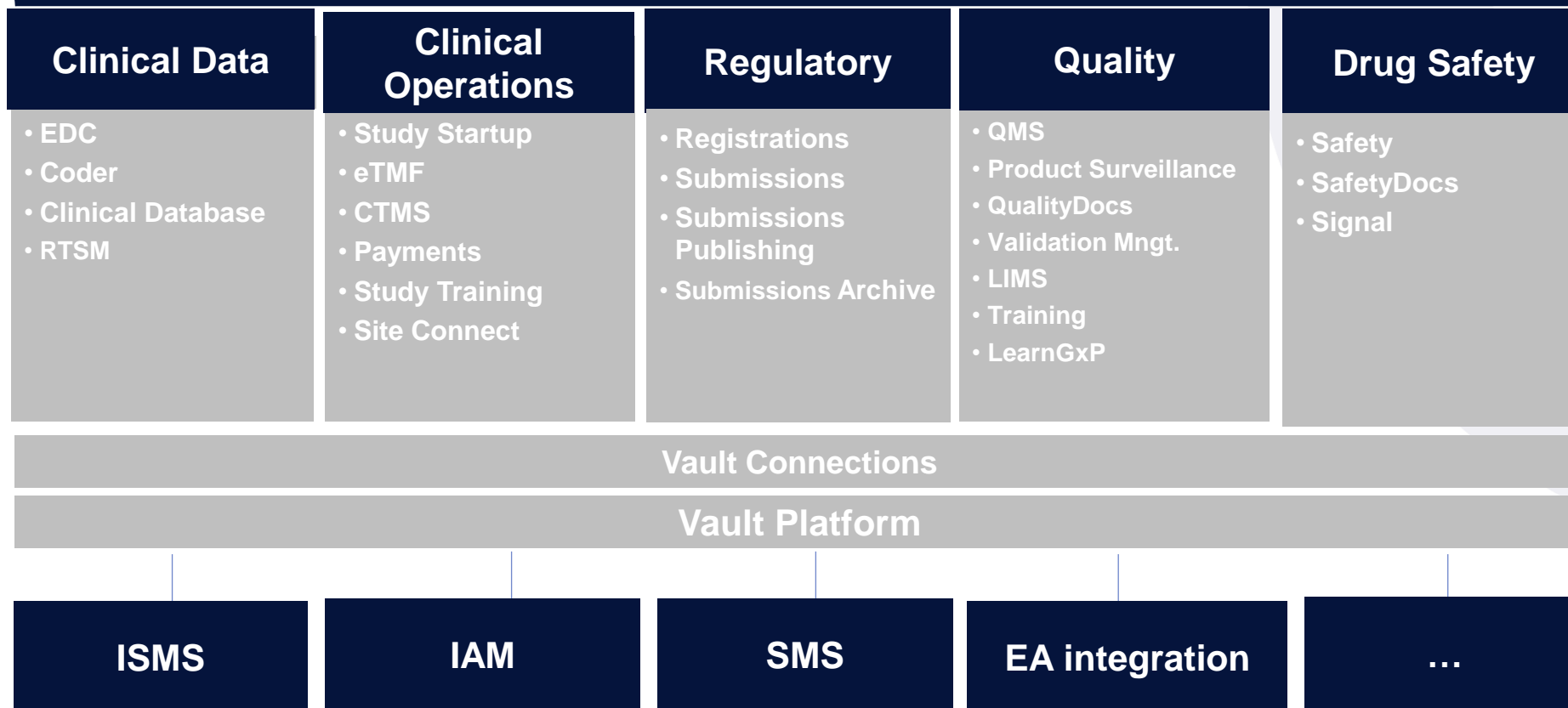
- EcoVadis gold rating since 2019

Life Science

- More than 20 years of experience in providing services to Life Sciences in areas of Product Supply, Regulatory Affairs and R&D

- Integrated view of business and IT

- Life Sciences is the strategic investment and growth area of INCONSULT

- Expertise in domain related product suits and technology platforms with a strong partnership ECO system

- Deep knowledge of regulatory compliance requirements

- Engaged in numerous projects at various Life Sciences customer

Veeva Solution Scope

Clinical Data	Clinical Operations	Regulatory	Quality	Drug Safety
• EDC • Coder • Clinical Database • RTSM	• Study Startup • eTMF • CTMS • Payments • Study Training • Site Connect	• Registrations • Submissions • Submissions Publishing • Submissions Archive	• QMS • Product Surveillance • QualityDocs • Validation Mngt. • LIMS • Training • LearnGxP	• Safety • SafetyDocs • Signal

Vault Connections

Vault Platform

ISMS	IAM	SMS	EA integration	…

Veeva Offering Overview

Project Management

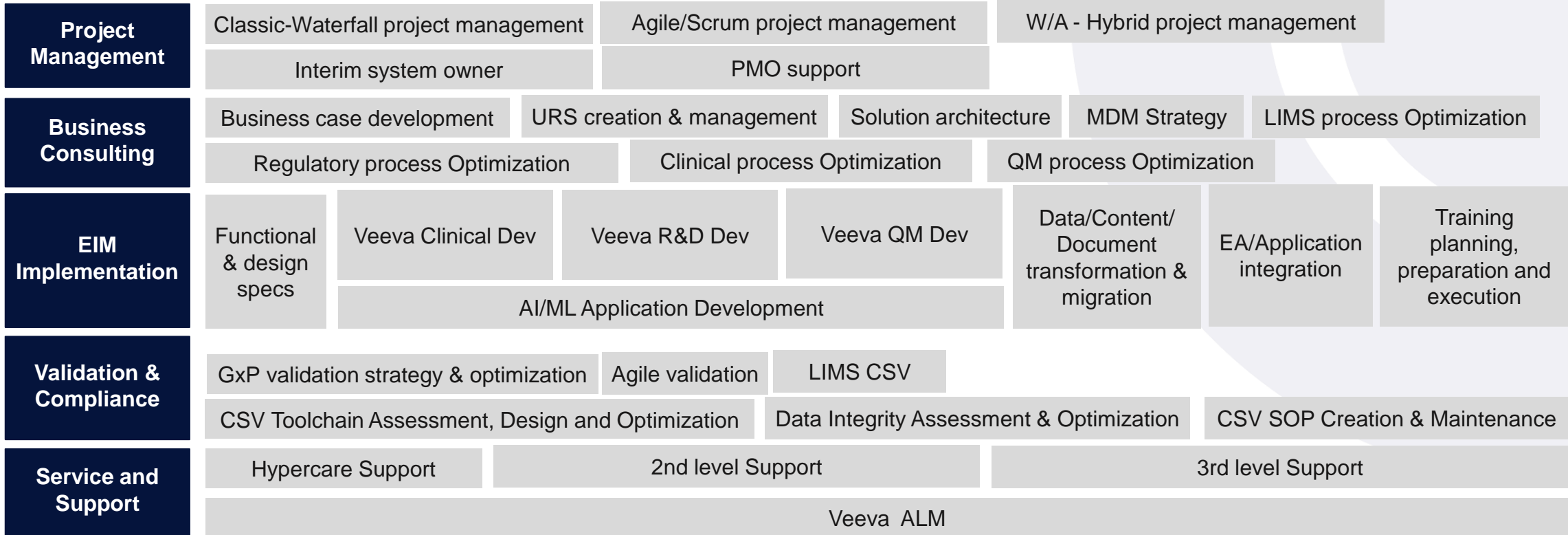**Business & Process Consulting**

Enterprise Information Management Application

Managed IT services

Compliance & Governance

Our promise: We deliver new or optimized capabilties of highest quality to executives and user so that they can work more easier, faster, errorfree and compliant.

Veeva Project Scope

Project Management	Classic-Waterfall project management	Agile/Scrum project management	W/A - Hybrid project management
	Interim system owner	PMO support	

Business Consulting	Business case development	URS creation & management	Solution architecture	MDM Strategy	LIMS process Optimization
	Regulatory process Optimization	Clinical process Optimization	QM process Optimization	

EIM Implementation

Functional & design specs	Veeva Clinical Dev	Veeva R&D Dev	Veeva QM Dev	Data/Content/ Document transformation & migration	EA/Application integration	Training planning, preparation and execution
	AI/ML Application Development					

Validation & Compliance

GxP validation strategy & optimization	Agile validation	LIMS CSV
CSV Toolchain Assessment, Design and Optimization	Data Integrity Assessment & Optimization	CSV SOP Creation & Maintenance

Service and Support

Hypercare Support	2nd level Support	3rd level Support
Veeva ALM		

More than 20 years of proven experience

Our Customers*

Project Management

Business & Process Consulting

Enterprise Information Management Applications

Support & Lifecycle Management

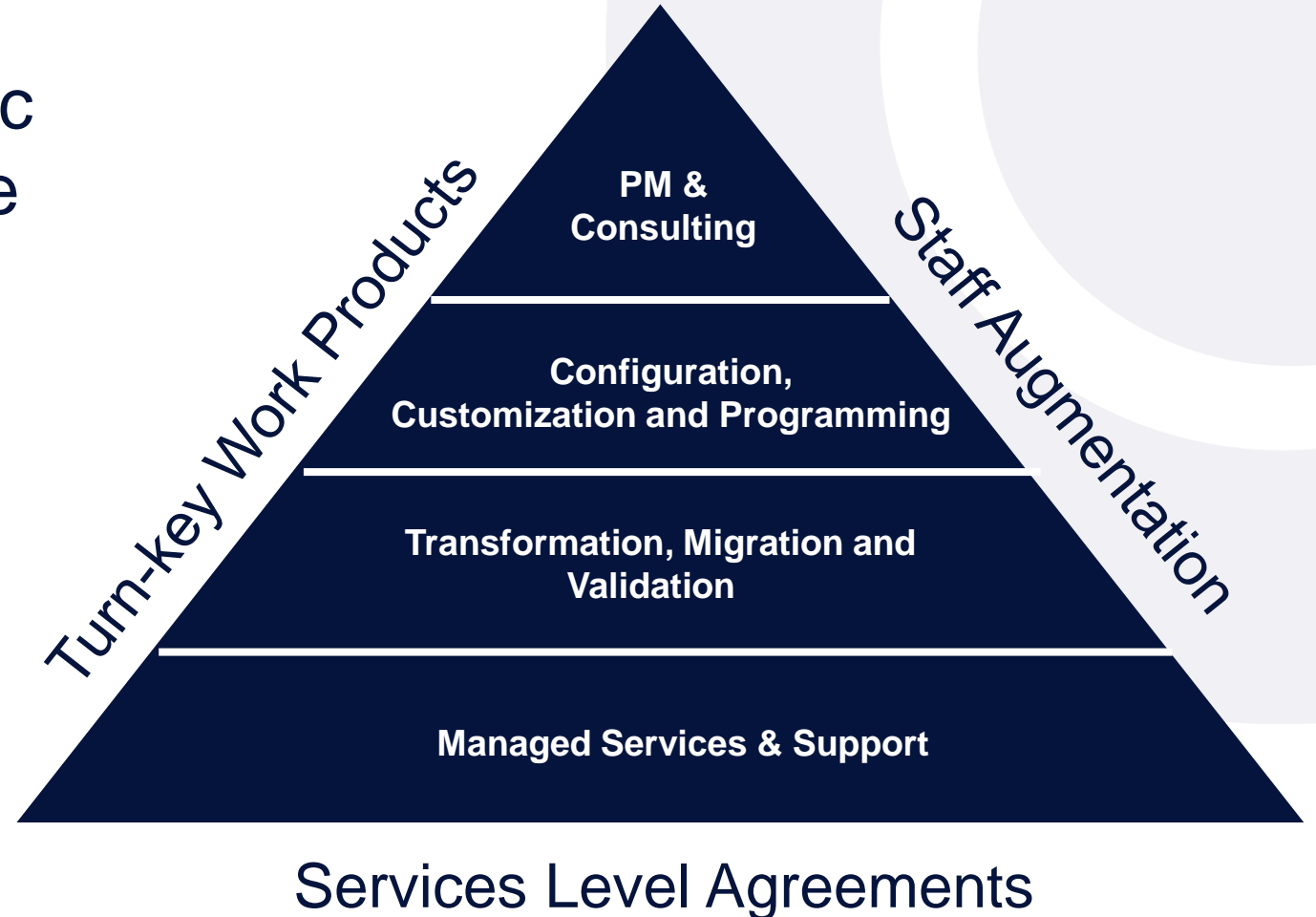**Compliance & Governance**

Our greatest asset, our customers - Once a customer, always a customer

Engagement Model

Depending on your specific needs, we can offer a wide range of engagement models.

Our consultants work on methods based on industry, yours or our own best practices.

Turn-key Work Products

Staff Augmentation

PM & Consulting

Configuration, Customization and Programming

Transformation, Migration and Validation

Managed Services & Support

Services Level Agreements

Application Lifecycle Management

Release Managers	Business Analysts	Validation Experts	Change and Training Manager	Configuration Architects
• Planning, Scoping, Coordination of Veeva and Customer Releases • Project Managers with depth experience with the Veeva method-ologies and Release Management • Agile Management of Releases with estab-lished methodologies (e.g., PMI, PRINCE2, SCRUM)	• Education of Release Features with Business Experts for Regulatory, Quality and Clinical • Managing Business Critical Requirements and finding and designing Solutions • Help maximizing value of the system by driving customer releases with combining both new capabilities and business needs	• Creation of Validation Documentation, Validation planning • Creation of Validation Test plans • Management in a risk based approach to ensure compliance while minimizing efforts • Creation of Validation Change Control	• Organizational Change Management • Creation of Training Materials and providing End User Training • Marketing of Benefits of new Releases	• Implementation or Configuration of Enhancements • Implementation or Configuration of new Features • Keeping system up to date technically and implement any new requirements • Build integrations to other systems