COME TO THE SOURCE, BECAUSE ...

... OUR FOCUS IS ON THE CUSTOMER.

Our goal is to make the qualification process a sucess for each of our cutomers. Your qualification project manager will begin with the project at an early stage, to help guide the project through the planning, preparation, and finally, the execution phases. We strive to provide our customers with the tools and support necessary to get their system qualified in as short a time as possible with the optimal resource expenditure.

... OUR QUALIFICATION PACKAGES ARE MODULAR, LIKE OUR MACHINES.

Dividella has standard qualification packages available to help meet your machine qualification needs. In addition to standard packages, additional supplementary documentation is available to „round out" a particular package. Risk Analysis and Design Review Workshops are examples of these supplementary materials.

However, Dividella can also assist you in analyzing your special requirements and then developing a customized offering that is individually tailored to meet your specific needs. For example, if you are attempting to implement the ASTM E2500 standard, Dividella can partner with you to develop a verification plan and testing strategy that matches your company's particular implementation approach.

Support from Dividella is more than just documentation. Our qualification specialists can support you at our site or yours with expert assistance to meet your needs during the execution phases as well.

... YOUR NEEDS MAY CHANGE OVER TIME.

Dividella can, of course, support our customers with a wide range of additional options and retrofits for our machines – to assist you as your packaging needs change. In addition to machine modifications, we can also provide the support necessary to advise in re-qualifying the new and or modified functionality. Your qualification project manager will assist you to develop a qualification strategy for the machine retrofit. We can support the project with an updated Risk Analysis, Design Documents and Testing Documents. A detailed description of the modifications is also provided to summarize all the necessary information for use in your internal change control process.

... RISK MUST BE MANAGED.

Risk and risk assessment are critical issues in today's regulatory and business environment. It is imperative from both a quality and business perspective that (project) risks are assessed correctly and mitigated appropriately.

Dividella has the knowledge and expertise to assist our customers during the risk assessment process and the technical know how to come up with cost effective solutions to mitigate those risks.

Our core values

As market leader for innovative pharma packaging solutions, we allow no compromises in the quality of our products and our customer service. With our engineering and packaging development expertise, we contribute to our customers' success. We act in partnership and we are personally responsible for the results of our work.

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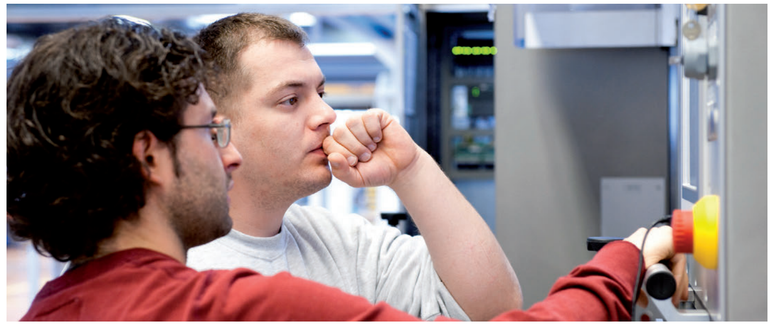
Dividella AG 03.2014

DIVIDELLA
KÖRBER SOLUTIONS

COME TO THE SOURCE

Dividella Qualification Services

WHO BETTER TO SUPPORT YOU DURING YOUR MACHINE QUALIFICATION PROJECT THAN THE ONES WHO KNOW YOUR MACHINE INSIDE AND OUT?



COME TO THE SOURCE
DIVIDELLA QUALIFICATION SERVICES

SELECTABLE QUALIFICATION MODULES – CUSTOMIZED TO MEET YOUR REQUIREMENTS

		MODULE 1	MODULE 2	MODULE 3
QP	Quality Plan	•	•	
FS	Functional Specification	•	•	
HDS	Hardware Design Specification	•	•	
SDS	Software Design Specification	•	•	
FAT	Documentation		•	
IQ	Documentation		•	
OQ	Documentation		•	
Risk Analysis	Workshop			
Trace Matrix	Documentation			
Design Review	Workshop			
FAT	Testing Execution			
Customer Site	Testing Execution			
ASTM	E2500 Support			
Qualification	Machine Retrofits			

CUSTOMIZED

QP Quality Plan 1 2 3

Document describes project scope, project organization, participant roles and responsibilities. Also includes a description of Dividella Quality Management System, schedule, document delivery process and change management process.

FS 1 2 3

Functional Specification describes the function of the system and how it will meet the requirements presented in the User Requirement Specifications.

HDS 1 2 3

Hardware Design Specification presents more detailed information on the electrical hardware design of the system. This information includes communication structures and interfaces to 3rd party equipment.

SDS 1 2 3

Software Design Specification includes information further explaining the control concept of the machine. Additionally, the safety structure, password concept, and shift register are detailed. Finally, the software structure and GMP relevant software function blocks are discussed.

FAT – Documentation 2 3

Testing documents for use as FAT testing at Dividella site. For test points, see IQ and OQ below.

IQ – Documentation 2 3

IQ testing documents for use as IQ (or other) testing at customer site. Test points include hardware, software installation verification, code review, software structure and software backup.

OQ – Documentation 2 3

OQ testing documents for use as OQ (or other) testing at customer site. Test points include GMP critical functions, safety functions, technical alarms, HMI, and access rights.

Risk Analysis – Workshop 3

Work with Dividella personnel to perform a patient safety risk analysis for your specific machine using your site RPN definitions. RA can be performed over "Web Ex" or at our site. Time required will vary based upon desired scope and machine complexity. Output of workshop will be a RA matrix and reports detailing critical items and RPN values before and after risk mitigation.

Trace Matrix – Documentation 3

A living document, it traces user requirements from the URS thru design documents and finally into testing documents. Updated throughout the duration of the project. *Included with Design Review Workshop and Report.*

Design Review – Workshop 3

Work with Dividella personnel to perform an in-depth Design Review and evaluation of URS points as compared to design. Review of all GMP relevant and critical machine functionality. Time required will vary based upon desired scope and machine complexity. Workshop should be performed at Dividella. Output of workshop is report delineating status of all URS points.
Includes Trace Matrix and meeting summary.

FAT – Testing 3

Dividella can manage the execution of the FAT including change management process, test scheduling and execution resources.

Customer Site – Testing Execution 3

Dividella can manage/support the execution of testing at the customer site including document management and execution resources.

ASTM – E2500 Support 3

Document modifications necessary to conform to a customer's particular implementation of ASTM E2500. Requires either a verification plan from the customer or a clearly defined scope document. ASTM E2500 is a standard concerned with a risk based, pragmatic approach to the qualification of equipment, systems and associated automation. The key concepts are focused on Good Engineering Practice, evaluation of risks to product quality/patient safety by the appropriate subject matter experts and verification of general machine functionality and critical aspects using a scientific and pragmatic process. The standard does not specifically define the "right" way to implement and thus there is wide latitude in terms of practice. Therefore, methods and procedures should be defined at the beginning of the project.

Qualification – Machine Retrofits 3

Documentation updates covering machine modifications and additions. Updates can include Risk Analysis, Design Documents, and Testing Documentation depending upon scope of project.