

NEWSLETTER

September 2015

Quality supervision (QS) and material testing

Success of a project or investment heavily depends on the ability to receive ordered material **at the right time** and **within the expected quality**, something which can definitely not be taken for granted especially when sourcing from a low cost country like China. The knock-on effect to the entire project schedule can be severe and it usually binds a vast amount of resources to deal with such problems. There needs to be a system in place which clarifies the following main points:

- What is required? (Material specification)
- Who can deliver it? (Supplier pre audit and evaluation)
- Definition of acceptance criteria? (Do we know the key parameters? Do we know how to check them?)
- Are acceptance criteria sufficiently defined in RFQ (Request for Quotation)?
- Does suppliers' staff know our acceptance criteria?
- What resources are available with the right skill set and tools to measure acceptance criteria?
- Where are tests performed? (At the vendors' workshop? At receivers end?)
- How to document results?
- Communicate deviations to the end user or project manager !



Specification of goods (definition of what is actually required)

When analyzing deviation in the QS process very often it is due to insufficient or unclear written specification that leads to disappointment and arguments. A clearly written and agreed specification will enable a clear communication with all stakeholders and also defines the acceptance criteria, which is a key success factor both for supplier as well as for customer.

In the picture on the right, there is an example of a DQ (Design Qualification) test plan with specification and acceptance criteria.

广州拉斯卡工程咨询有限公司

RASCHKA

模板编号: TM-Q-0016

项目名称	热处理验收记录			
项目编号				
单元	设备位号	图纸号		
热处理前设备检查及要求:				检查结果
需热处理主体按图纸要求焊接完毕; 预焊件已焊; 试板已齐全;				<input type="checkbox"/> 是; <input type="checkbox"/> 否
热处理保护措施已完善。				<input type="checkbox"/> 是; <input type="checkbox"/> 否
焊缝检查及无损检测已合格;				<input type="checkbox"/> 是; <input type="checkbox"/> 否
热处理工艺文件编制完成;				<input type="checkbox"/> 是; <input type="checkbox"/> 否
热处理单位具备相应的资质。				<input type="checkbox"/> 是; <input type="checkbox"/> 否
其他:				<input type="checkbox"/> 是; <input type="checkbox"/> 否
按下列标准及规范				

Supplier evaluation

Finding the right supplier for your specific needs is definitely a key success factor for any kind of project. Lonza Engineering has audited and evaluated the supplier market in China for more than 15 years and keeps track of companies performance either through its own experience or using information from partnering companies. Sourcing from low cost country requires a somewhat more careful evaluation process and would need to focus initially more on supplier's capability, reliability and track record before talking about commercial items. Another aspect is the high fluctuation of supplier's workforce which can make previous customer references meaningless. It is therefore important to look at several aspects when conducting (pre) audits, the following list is just an example of what we believe should be looked at when performing an audit of a potentially new supplier

- Factory Profile
- Ownership
- Tax register certificate
- Business certificate
- Business relations
- Credit check
- Management
- Training record
- Turnover rate (fluctuation) of workforce
- Quality Assurance System
- Machinery conditions
- Capabilities
- Workflow
- Documentation
- Reference list and previous customer interview

Focus on having at least 2 capable suppliers defined before starting commercial discussions, just having some low performing suppliers as backup will not give you the confidence to utilize full negotiation power

With average turnover managed for our clients being more than 50 Mio US\$/year, Raschka Engineering has a wide network and a good local supplier list which can be made available to our customers.



QS inspector looking for training records and welder qualification

Acceptance criteria

First and foremost we need to understand what it is we need to purchase and for that purpose a specification needs to be written. Information should be provided about the key parameters which will need to be measured (tested) against the pre defined values and ranges → **acceptance criteria**

Such requirements are some times defined by standards or design codes, but very often this will not be sufficient and therefore additional criteria's will need to be defined.

Definition of acceptance criteria must be an integrated part of the equipment specification and also requires a pre-definition of what needs to be tested or verified before goods are accepted. We also need to make this clear during the bidding process to ensure the supplier fully understands the acceptance criteria and quote (deliver) the material/product under the stipulated requirements. Testing / verification method also needs to be clarified as this could potentially require a third party involvement and ultimately impact on cost and delivery time when not addressed at an early stage.

Acceptance Criterion for Mechanically Polished Hygienic Tubing, Fittings and Process Components

Nominal Size in.	O.D.		Wall Thickness		Squareness Face to Tangent		Off Angle		Equivalent Angle, deg	Off Plane		Centerline Radius	
	in.	mm	in.	mm	in.	mm	in.	mm		in.	mm	in.	mm
1/4	± 0.005	± 0.13	+0.003/-0.004	+0.08/-0.10	0.005	0.13	0.009	0.23	2.1	0.030	0.76	0.563	14.30
3/8	± 0.005	± 0.13	+0.003/-0.004	+0.08/-0.10	0.005	0.13	0.012	0.30	1.8	0.030	0.76	1.125	28.58
1/2	± 0.005	± 0.13	+0.005/-0.008	+0.13/-0.20	0.005	0.13	0.014	0.36	1.6	0.030	0.76	1.125	28.58
3/4	± 0.005	± 0.13	+0.005/-0.008	+0.13/-0.20	0.005	0.13	0.018	0.46	1.4	0.030	0.76	1.125	28.58

Quality supervision and Acceptance test

Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) are methods to ensure that the purchased product will meet the pre defined acceptance criteria. Such methods are usually applied for equipment and fully functional systems or modules. For some key components or critical bulk material (valves, fittings, instruments, etc) it is essential to perform tests and quality control during the manufacturing process because a mayor deviation observed during FAT or SAT could potentially mess up the project schedule.

Raschka Engineering regularly uses its trained workshop personnel or engineering staff to perform quality supervision during the entire manufacturing process at supplier's workshop. Red flag is raised by our own people as soon as a deviation is observed or agreed milestones have slipped.



Monitoring manufacturing process of hastelloy heat exchangers(a cost engineered design made by Raschka Engineering)

An effective QS system will reduce the risk of errors made during manufacturing process and will ensure goods are produced first time right within the agreed delivery time.

Documentation

A common problem with Chinese suppliers is the relatively poor documentation. When asking for a quotation one gets not much more than a few commercial lines attached to a product brochure leaving a lot of uncertainties whether or not the product will meet the expectations. Once the order is placed and the goods delivered the final documentation is not showing any details, material certifications are missing and spare part lists do not exist. It is therefore also advisable to mention the expected document list in the purchasing contract and to ensure that the supplier is aware of the kind of drawing details you want to see. Especially for highly regulated cGMP facilities a very detailed and traceable documentation with all material certifications is of absolute importance.

Make the documentation list become an integrated part of the deliverables and stipulate this explicitly in the purchasing contract, do not issue final payment unless you have thoroughly checked quality and completeness of the documentation received



Testing rigs available at Raschka Engineering



Testing of ceramic column packing (8 out of 10 samples failed the pH range tested!)



Raschka Engineering's testing rig for pumps, valves and instruments



Testing of PTFE distributor for distillation column

Civil design review and construction supervision

Despite the fact that Raschka Engineering has no design license nor is it a certified supervision company, but our experts are experienced in civil design and are able to “ask the right questions”. For a client who is faced with a boiler chimney which is not built according to design standards despite construction supervision by a certified body. Raschka Engineering is engaged in evaluation of design for repair, cost estimation, coordination of work, reporting, technical support for legal consultant and cost control.



Testing tools owned and regularly used by Raschka Engineering



Measuring shaft alignment between motor and pump



Check and document welding quality inside tube (Boroscope)



Material test on PTFE lined pipes and fittings



High Voltage test to check integrity of glass lined equipment

In this context, Raschka Engineering's service could include:

- Engineering and design support
- Sourcing consultancy
- Quality control and consultancy
- Supplier supervision
- Supplier evaluation and data sharing
- 3rd party inspection
- Technical Due Diligence
- Material Testing Service
- Boroscope Service
- Equipment/System Validation
- Continuous improvement and optimization

Please feel free to contact us in order to discuss your needs with Raschka Engineering's expert team, we would be very happy to share our experience in the field of quality supervision and supplier network

An extensive service list is available on our website:

<http://www.raschka-engineering.com>



Raschka Engineering Ltd

Raschka Engineering Ltd. Liestal, Switzerland (previously known as Lonza Engineering) now reflects the superior and well known Raschka FBI technology in its name together with its wholly owned subsidiary Raschka Engineering & Consulting Co., Ltd, China provides customer oriented services with a professional, experienced and highly motivated engineering team. We have 20 years of successful project management experience in China which makes us a perfect partner for the chemical, pharmaceutical and biopharmaceutical industry. A board range of services with a project reference list underlining our capabilities is available upon request.

Raschka Engineering has successfully managed multiple complex projects such as continuous operating plants for the production of food and feed additives as well as active pharmaceutical ingredient plants including waste gas and liquid waste treatment facilities.

Contacts

Raschka Engineering Ltd
Dachsweg 12 CH-4410 Liestal, Switzerland
Tel: +41 61 534 9913
or +41 79 750 9845
Email: info@raschka-eng.com
Website: <http://www.raschka-engineering.com>

Raschka Guangzhou Engineering & Consulting Co. Ltd
Room 401, South Tower, Peace Business Centre, No. 898 of Guangzhou Avenue South, 510305, Guangzhou, China
Tel: +86 20 8966 4288
Fax: +86 20 8966 4278
Email: info@raschka-eng.com
Website: <http://www.raschka-engineering.com>