# The terms "supplier", "service provider" and "outsourced process" are all treated the same and called "supplier" in the following.

- \* terminology from MDSAP AU P0002 applies
- \*\*Grades as per Common Terminology Criteria for Adverse Events (CTCAE) 0
- \*\*\*MDSAP AU P0037 (NC Grading)

Are the purchased materials, components, subassemblies or services from suppliers which DO operate under the own\* QMS?

No, assess the severity of harm, if the purchased materials, components, subassemblies or services would fail. Would the severity cause a harm rated Grade\*\* below 3?

NO. Are the purchased materials, components, subassemblies or services from suppliers having an INDIRECT impact only\*\*\*

NO. Will the purchased materials, components, subassemblies or services from suppliers be fully verified by subsequent monitoring or measurement?

NO, supplier will be considered CRITICAL

Will the purchased materials, components, subassemblies or services from suppliers be custom made, i.e., based on customer's specification?

YES, not applicable to supplier controls, the production and service controls of the own QMS applies, including internal auditing.

YES, supplier will be considered MINOR

### Minimum requirements are

- · Supplier qualification AND
- Periodical supplier evaluation AND
- · Receiving inspection (Quality, Integrity, Identity).

YES, supplier will be considered MAJOR

### Minimum requirements are

- Supplier qualification AND
- Periodical supplier evaluation AND
- · Receiving inspection (Quality, Integrity, Identity) AND
- Incoming inspection / Verification of service or process.









www.quality-on-site.com

### YES, minimum requirements are

- Supplier qualification AND
- Periodical supplier evaluation AND
- Receiving inspection (Quality, Integrity, Identity) AND
- Incoming inspection / Verification of service or process.

#### In Addition

- Quality Agreement including change agreement, process and test method validations AND
- supplier audit.
- Verify with notified body, if supplier is to be notified.

## NO, minimum requirements are

- Supplier qualification AND
- Periodical supplier evaluation AND
- Receiving inspection (Quality, Integrity, Identity) AND
- Incoming inspection / Verification of service or process. In addition

## · Accreditation/certification and certificate of analysis, OR

 Quality Agreement including change agreement, process and test methods validations and supplier audit.