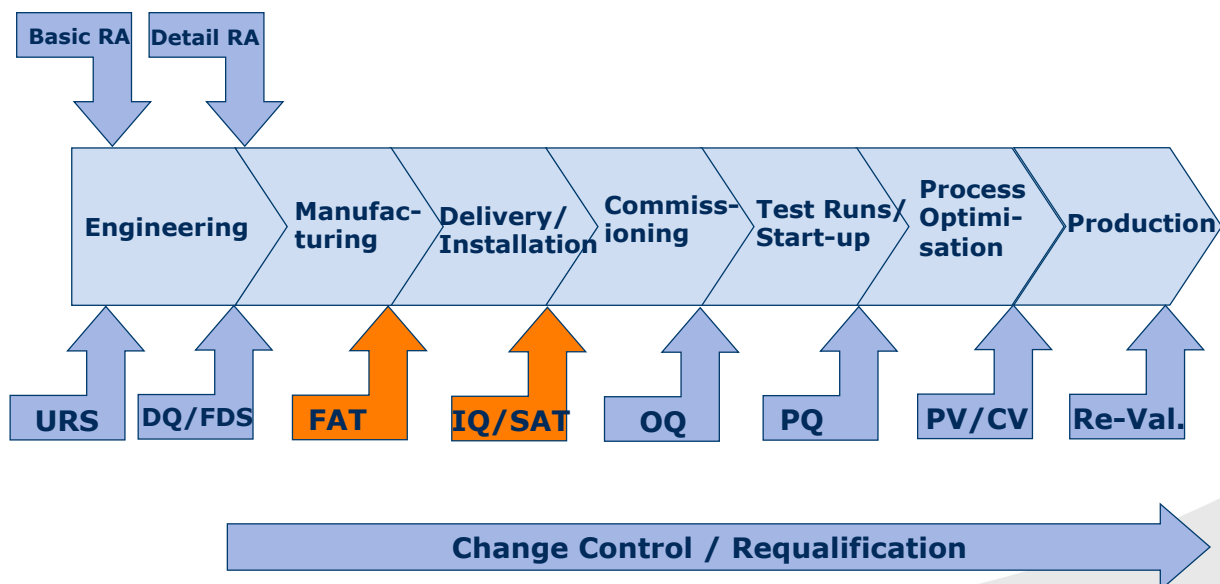


FAT – Factory Acceptance Testing SAT – Site Acceptance Testing

Dr. Ingrid Walther

Factory Acceptance Testing - FAT
Site Acceptance Testing - SAT

FAT and SAT - Important Milestones in the Project Schedule



FAT/SAT - Explanation

FAT = Factory Acceptance Test

Testing of equipment and relevant documentation **at the vendor's workshops** against the requirements of an approved test protocol

SAT = Site Acceptance Test

Testing of equipment and relevant documentation **at the site of use of the equipment** against the requirements of an approved test protocol.

Regulatory Requirements

EU-GMP-Guide Annex 15

Factory acceptance testing (FAT) / Site acceptance testing (SAT)

3.4. Equipment, especially if incorporating novel or complex technology, may be evaluated, if applicable, at the vendor prior to delivery.

3.5. Prior to installation, equipment should be confirmed to comply with the URS/ functional specification at the vendor site, if applicable.

What does this mean?

- FAT is not a general requirement, not required for
 - small, standard equipment
 - equipment that cannot be readily installed at the vendor's site (e.g. HVAC-Systems)
- When should FATs be done?
 - for complex equipment
 - equipment with new technology
 - If transportation is important, e.g. from Europe to Asia!
 - when installation on site is complicated and equipment has to go back to the vendor when it fails

Regulatory Requirements

EU-GMP-Guide Annex 15

Factory acceptance testing (FAT) / Site acceptance testing (SAT)

3.6. Where appropriate and justified, documentation review and some tests could be performed at the FAT or other stages without the need to repeat on site at IQ/OQ if it can be shown that the functionality is not affected by the transport and installation.

3.7. FAT may be supplemented by the execution of a SAT following the receipt of equipment at the manufacturing site.

What does this mean?

- When an FAT is performed, tests do not have to be repeated for IQ and OQ, if
 - transport and installation did not have a negative impact
 - tests are performed and documented in a GMP-compliant manner
 - supervision by the qualification team
- SAT should be done after installation on site

Remark: This is normally when the supplier gets paid, however, the contract should include that final payment is done after successful OQ (PQ) testing

FAT / SAT - General scope of work

Testing equipment for compliance with URS / FDS and GMP requirements by checking:

- Completeness of installation
- Dimensions and correct design
- Materials and surfaces
- Functional tests, performance tests and safety functions
- Completeness of documentation

FAT / SAT - General scope of work

- Testing according to approved test protocols.
- Test protocols approved by all involved parties (user, manufacturer, engineering partner - if applicable)
- SAT may include tests from FAT under „real“ conditions. Not all conditions can be simulated in manufacturers workshop!
- Reporting of results and deficiencies
- Target of FAT: Approval for shipping to installation site
- Targets of SAT: Final acceptance, proof of process guarantees, hand-over from manufacturer to user

FAT / SAT - Suggested contents of Test plans

- Introduction incl. short process description
- Scope of the testplan
- Deficiency handling
- Responsibilities
- Identification of reference instruments and test personnel
- Test description and test result summary sheet
- Attachments (forms for test raw data, SOPs, etc.)

Explanation: Deviations vs. Deficiencies

FAT / SAT – Test Definition

- Time schedule for the tests
- What has to be tested and what are the acceptance criteria?
- How shall the tests be executed? Test conditions?
- According to which guidelines and standards?
- Who is responsible for test preparations, delivery of test material and test execution?
- What has to be done when a test fails?
- How are the test results to be reported?

FAT / SAT - Execution of Tests according to Test plans

- The equipment is generally operated by supplier's personnel
- Functional tests are witnessed / supervised by personnel of the user
- Other tests/checks are executed by either manufacturer or user
- Qualification staff of user shall be involved in testing to avoid double testing in subsequent IQ / OQ / PQ
- Tests may have also the purpose of training for the users personnel (participation of operators, technical and maintenance staff is recommended)

FAT / SAT - Reporting and Deficiency Handling

- All results from the tests have to be reported in the test protocol
- When tests could not be carried out as planned: describe why and how it has been done instead.
- If acceptance criteria are not met: write down in a deficiency form
- Deficiency forms must have clear indication of deviation, actions to solve the deviation, time lines and responsibilities
- Requirements for re-testing and final approval have to be stated in the deficiency form

DEFICIENCY FORM

Object:		Date:
Deficiency number:		
Description of deviation		
Name / Signature..... Date.....		
Consequence of deficiency		
Proposed solution (vendor)		
Representative (vendor)		
Name / Signature.....		Date.....
Solution accepted ☐		Solution not accepted ☐
Comments		
Representative (purchaser)		
Name / Signature.....		Date.....
Implemented solution (vendor)		
Name / Signature..... Date.....		
Result accepted ☐		Result not accepted ☐
Comments		
Approval (Purchaser Representativ)		
Name / Signature.....		Date.....
Deficiency closed (Vendor Representativ)		
Name / Signature		Date.....

FAT / SAT - Prerequisites for successful execution

- Sufficient information flow between manufacturer and user during the engineering and manufacturing phase
- Clearly documented test conditions and acceptance criteria (Test plans)
- Frequent inspections during manufacturing
- Well prepared equipment (readiness for tests!) and availability of necessary installations (e.g. media supply) and test material
- Clearly defined responsibilities and experienced personnel on all sides

Project Example

Ampoule Filling Line

- The Filling line consists of the following major equipment:
 - Ampoule washing machine
 - Depyrogenation tunnel
 - Accumulation belt
 - Filling machine with sealing station
 - Magazining station
- ⇒ All major components have been subject to functional tests during FAT

Project Example

Ampoule Filling Line - Technical Data -

Product: **Small Volume Parenterals (SVP)**

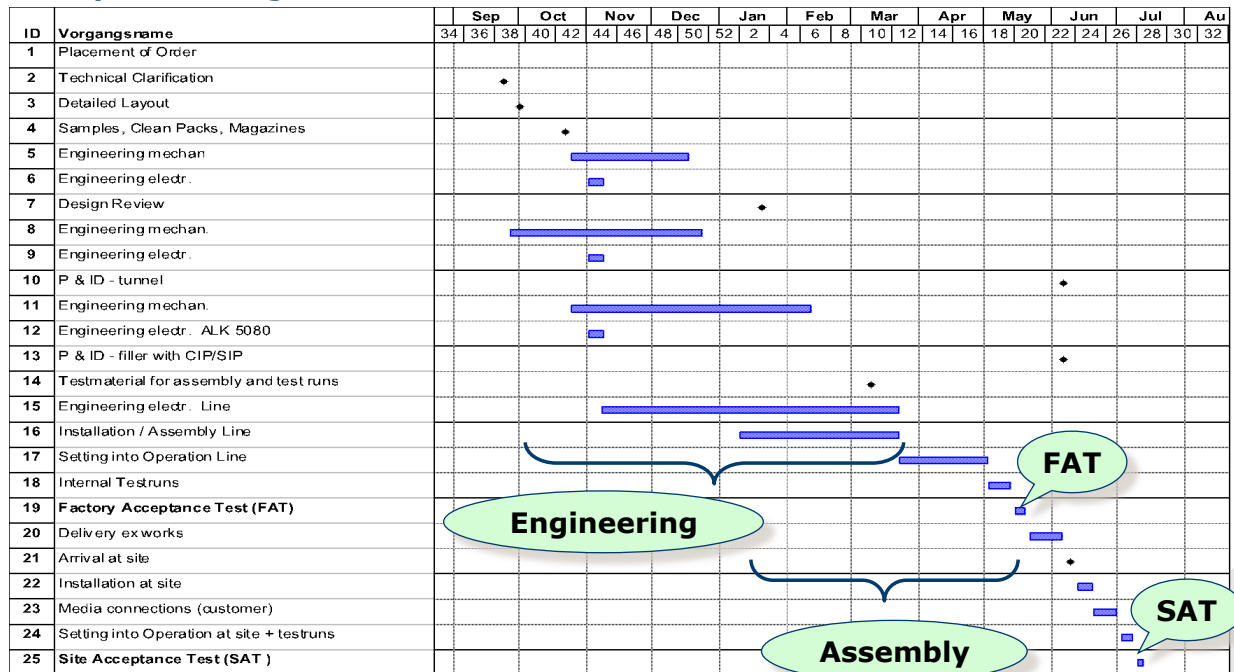
Filling capacity: **approx. 10.000 - 20.000 ampoules / hour**

Product sizes: **1 - 20 ml**

CIP/SIP: **fully automated**

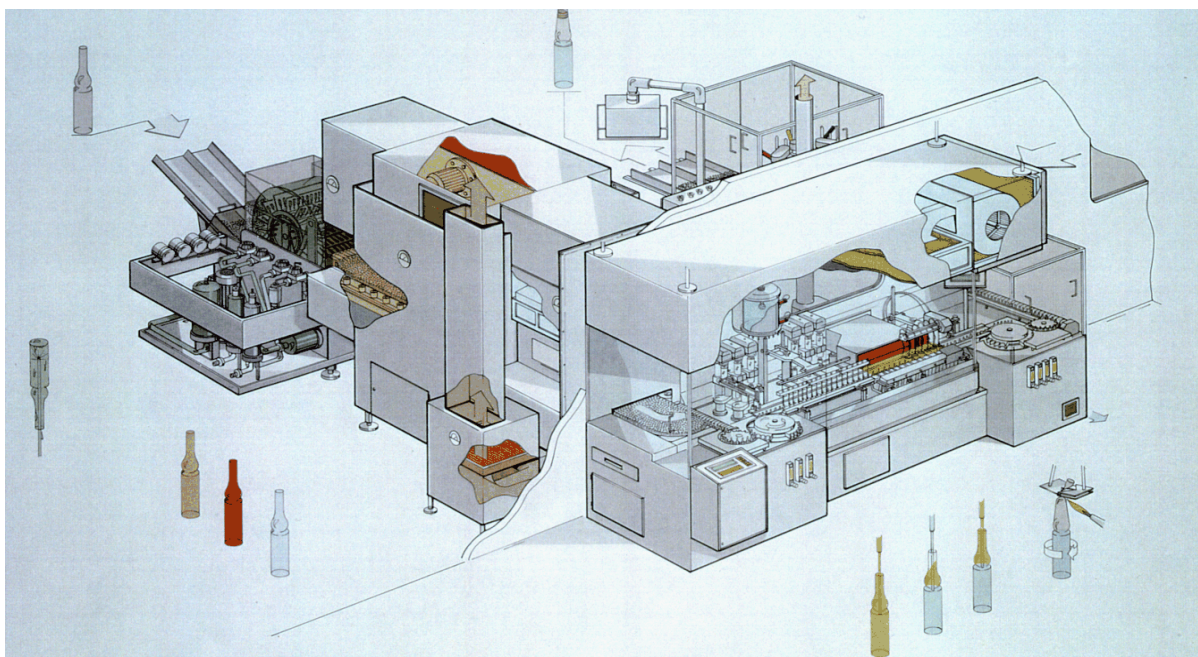
IPC: **Semi-automated In-process Control**

Project Example Ampoule Filling Line - Time Schedule -



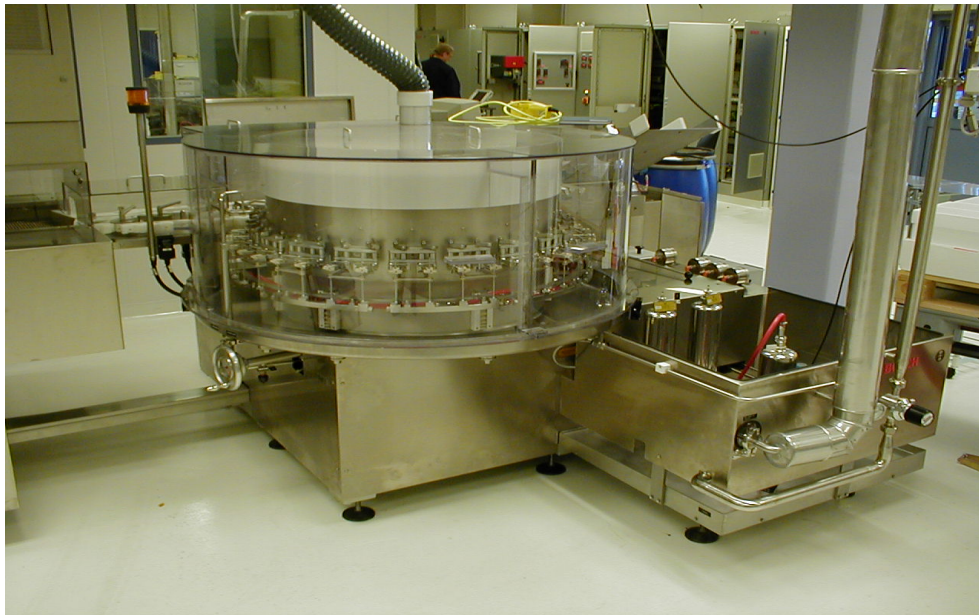
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Project Example Ampoule Filling Line - Schematic Drawing -



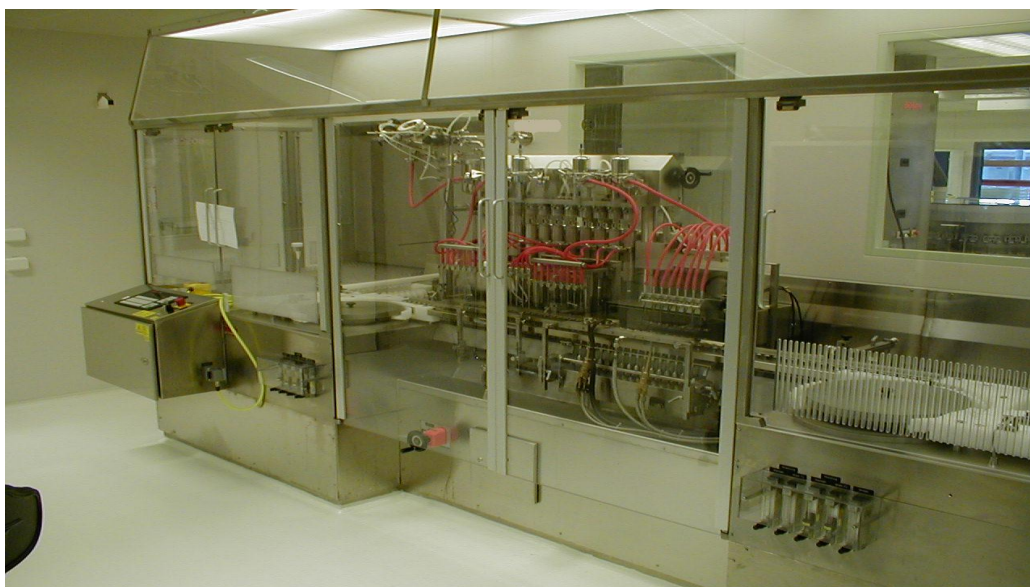
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Project Example
Ampoule Filling Line - Washing station -



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Project Example
Ampoule Filling Line - Filling stations + sealing station -



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Project Example

Ampoule Filling Line - FAT the execution procedure

- Checking of calibration status of reference instruments
- Test execution according test plan and SOPs
- Documentation of results (fill in forms, criteria fulfilled yes/no)
- Documentation of problems / observations in deficiency forms
- Repetition of tests, documentation of re-test results
- Closing of deficiency form by solving of problems

Project Example

Ampoule Filling Line - FAT Test Protocol

Title	Doc.nr./version	Page
Test Plan: Factory Acceptance Test Ampoule Filling Line	00000/00	1(1)
Issued by/Sign	Date	Valid from
Validation Representativ - Vendor		01-01-xx
Reviewed by/Sign	Date	Replace Doc.
QA –Responsible – Vendor		New doc.
Reviewed by/Sign	Date	
Validation Representativ – Purchaser		
Reviewed by/Sign	Date	
Project Manager - Purchaser		
Approved by/Sign	Date	
Production Manager – Purchaser		
QA Approved by/Sign	Date	
QA – Responsible - Purchaser		

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Title Test plan: Factory Acceptance Test Ampoule Filling Line	Doc.nr./version 00000/00	Page 1(1)
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Project Example

Ampoule Filling Line - FAT Test Protocol

6. Reference instruments that have been used during the FAT

Reference instruments that have been used during the FAT must have a calibration certificate, traceable to national standard. List in the table below all instruments that have been used, and attach a copy of the calibration certificate.

Instrument (Type, Model, Serial No)	Last calibration date	Calibration Expire date	Calibration certificate No	Sign/ date

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Project Example

Ampoule Filling Line - FAT Test Protocol

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7. Identification of all personnel involved in the FAT

All personnel involved in the FAT will be identified in the relevant data sheet.

name	dept./company	signature	sign	date	involved in				comment
					W	T	F	O	
legend:	W = washing machine T = tunnel F = filling machine O = Other (please comment)								

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Project Example

Title Test Plan: Factory Acceptance Test Ampoule Filling Line	Doc.nr./version 00000/00	Page 1(1)
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8. Summary of tests

no.	Reference URS	Scope	Procedure	Acceptance criteria	Reference to rawdata	Results comply (y/n)	Test done Date / Sign	Deviation no.
1	Annex #x, x.xx x.xy x.xz	Performance test for 10 ml ampoules t $\approx$ 60 min	SOP xx	10 ml ampoules: 10.200 good ampoules/h with water at room temperature (reference DIN 8782)				
		Performance test for 10 ml ampoules t = 10 min after a previous running time of 1h	---	97% reliability 10 ml ampoules: 11.640 good ampoules/h with water at room temperature				
		Performance test for 20 ml ampoules t $\approx$ 60 min	SOP xx	20 ml ampoules: 8.925 good ampoules/h with water at room temperature (reference DIN 8782)				
		Performance test for 20 ml ampoules t = 10 min after a previous running time of 1h	---	97% reliability 20 ml ampoules: 10.185 good ampoules/h with water at room temperature				

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Project Example

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no.	Reference URS	Scope	Procedure	Acceptance criteria	Reference to rawdata	Results comply (y/n)	Test done Date / Sign	Deviation no.
2	Annex #x, x.xa	Format change over and equipment set-up	standard format change will be executed	each format change part can be changed and adjustment is possible t $\leq$ 2 h with 2 trained persons + time for test run and fine tuning				
3	Annex #x, x.xb	Check of noise level	Test performed by Purchaser	noise level 75 $\pm$ 3 dB (A)				
4	Annex #x, x.xs	Documentation review	---	Internal check out documents (ICD) and preliminary instruction manuals are available				
5	Annex #x, x.xg	Check of surface roughness	Cloth test performed by Purchaser	when wiping dry the filling line, using a moist cloth, nothing of the cloth must get caught by roughness or ruggedness				

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Project Example

Ampoule Filling Line - FAT General Tests

- Visual checks (completeness, dimensions, surfaces, etc..)
- Machine start-up and shut-down
- Emergency stop tests: all emergency stop buttons accessible and functioning?
- Capacity Test (1 hour)
- Format change over and re-start
- Sound level checks
- Alarm / Interlock check, Emergency stop test
- Documentation review

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Project Example

Ampoule Filling Line – FAT specific additional tests

- Functional tests washing machine (spraying pattern, transport functions, etc. ...)
- Functional test depyrogenisation tunnel (pressures, air velocity, temperatures, HEPA filters, etc.)
- Testing of filling accuracy
- IPC functional test (weighing check for „out of specification ampoules“)
- CIP / SIP functionality (valve sequence, temperatures, etc..)
- N2 blanketing stations (gas flow check)

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Factory Acceptance Test according to document , location:
 Date:
 Equipment: Page 1 of 1

Project Example

FAT - Ampoule Filling machine

Punch list to FAT for , serial no. xxxxx.

The following is a conclusion of observations/findings/questions found during the FAT of , performed during:

Distribution List:

Vendor	Purchaser

Participants:

Vendor	Purchaser

Point	FAT test ref.	Description	Responsible for action (V or P), and completion date
1.	FAT- xx		V until
2.	FAT- xx		V until
3.	FAT- xx		V until
4.	FAT- xx		V before SAT
5.	FAT- xx		V before SAT
....	FAT- xx		

Above issues incl. responsibilities and completion dates agreed and accepted by:

For Vendor:

For Purchaser:

Signature _____

Date _____

Signature _____

Date _____

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Project Example

SAT - Summary of Testing

- Documentation Review: completely delivered? updated?
- P & IDs: comparison of internal piping connections with P&ID
- Utilities: check, if connections are correct
- Software: Update and interface check with plant software
- Cabling: connections between components and to external instruments and plant power system checked
- Check of outstanding issues (e. g. deviation forms) from FAT
- Emergency stop tests: all emergency stop buttons accessible and functioning?
- Performance test of complete line (3 hours).
- Noise level check: Level below 75 dB(A)
- Electro magnetic interference check

Common problems in FATs and how to avoid them

Problem	Solution
Equipment has not been completed by the vendor. Necessary Pre-checks are not completed	Define proper time schedule, supervise progress + ensure sufficient communication
Testing material (ampoules, plastic films, granulate, etc ..) is not available for FAT	Specify quality, amount and delivery time as early as possible
Required utilities (steam, cooling water, air, etc..) are not available	Specify quality and amount of necessary utilities and provide them for test

Common problems in FATs and how to avoid them

Problem	Solution
Equipment does not fit the spec, (misunderstandings? unqualified vendor?)	Thorough check of specifications → DQ Selection of adequately experienced vendor Audit the vendor and qualify him
Specified tests cannot be executed due to "protocol error"	Sufficient checking and approval of testplan (by technical and validation dep.)
Testplans are too "complicated / awkward", not practical	Ensure easy understandable test plan by cross check for suitability

Common problems in SATs and how to avoid them

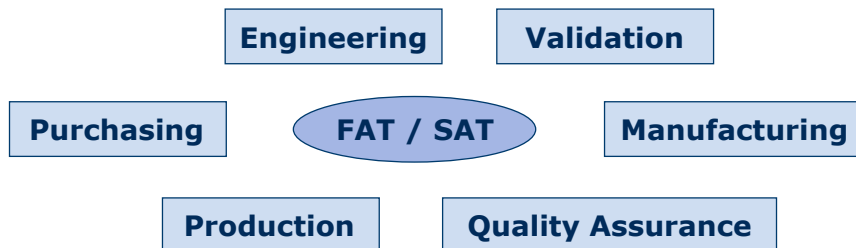
Problem	Solution
The plant is not ready (building, rooms, utilities,), no real product, missing approvals	Time scheduling and progress supervision in all areas. If necessary delay delivery
Staff (operators, maintenance) not sufficiently trained or not enough personnel available to support trials	Early recruiting and planning in of resources
Test fails because site specific conditions were not considered in planning	Thorough check of URS with regard of site specific conditions (e.g. media press.)

Common problems in SATs and how to avoid them

Problem	Solution
Equipment does not arrive on time due to failed FAT, rework or other reasons	Consider possible delays in planning. Prepare alternative activities
Equipment has been damaged during transport or parts are missing	Choose reliable freight forwarder, correct packing + protection Check transport ways before start of delivery
Equipment has been installed incorrectly	Choose qualified installation company. Preferably involve vendor of equipment

How to ensure smooth preparation/execution of FAT/SAT?

Ensure that all involved parties participate in the writing and approval of the test protocols:



Ensure that they understand each other - that they talk the same „language“!

FATs and SATs are important milestones in the supply process which ...

- ... test the quality of the supplied equipment and the conformity with specifications and GMP-requirements
- ... define release of payments (include successful completion of qualification!) and hand-over of responsibilities
- ... serve as a basis for later qualification steps - reduction of test scope + reduction of probability of deviations
- ... ensure safe and reliable production processes and products

Contact:
Pharma Consulting Walther
Dr. Ingrid Walther
Rosenweg 36
61381 Friedrichsdorf – Germany
+49-(0)6172-958281
+49-(0)172 654 8834
www.consulting-walther.com
iw@consulting-walther.com



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