BRCGS Product Safety Management

VALIDATION & VERIFICATION

PRE-COURSE HANDOUT

1 DAY COURSE

VIRTUAL TRAINING

2021

PRODUCT SAFETY MANAGEMENT
VALIDATION & VERIFICATION

1-Day Validation and Verification Virtual Training Course

For more information about BRCGS,
contact: BRCGS
Second
Floor 7 Harp
Lane
London EC3R 6DP

Tel: +44 (0) 20 3931 8150
Website: www.brcgs.com

[1]BRCGS is a trading name of BRC Trading Ltd.

CONTENTS

DEFINITIONS

VALIDATION

- **Codex:**
  Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome (CAC/ GL 69 – 2008)
- **BRCGS**
  Obtaining evidence through the provision of objective evidence that a control or measure, if properly implemented, is capable of delivering the specified outcome. Generally, scientific-based proof that an activity or action will mitigate a hazard

Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether proposed control measures are capable of achieving their desired outcome or target. It involves measuring performance against a desired outcome or target. Validation proves whether a proposed strategy will be effective in controlling a specified problem (hazard). Within validation, the result of the comparison may require a judgment of value regarding whether or not to accept the obtained result compared to a threshold or limit.

VERIFICATION

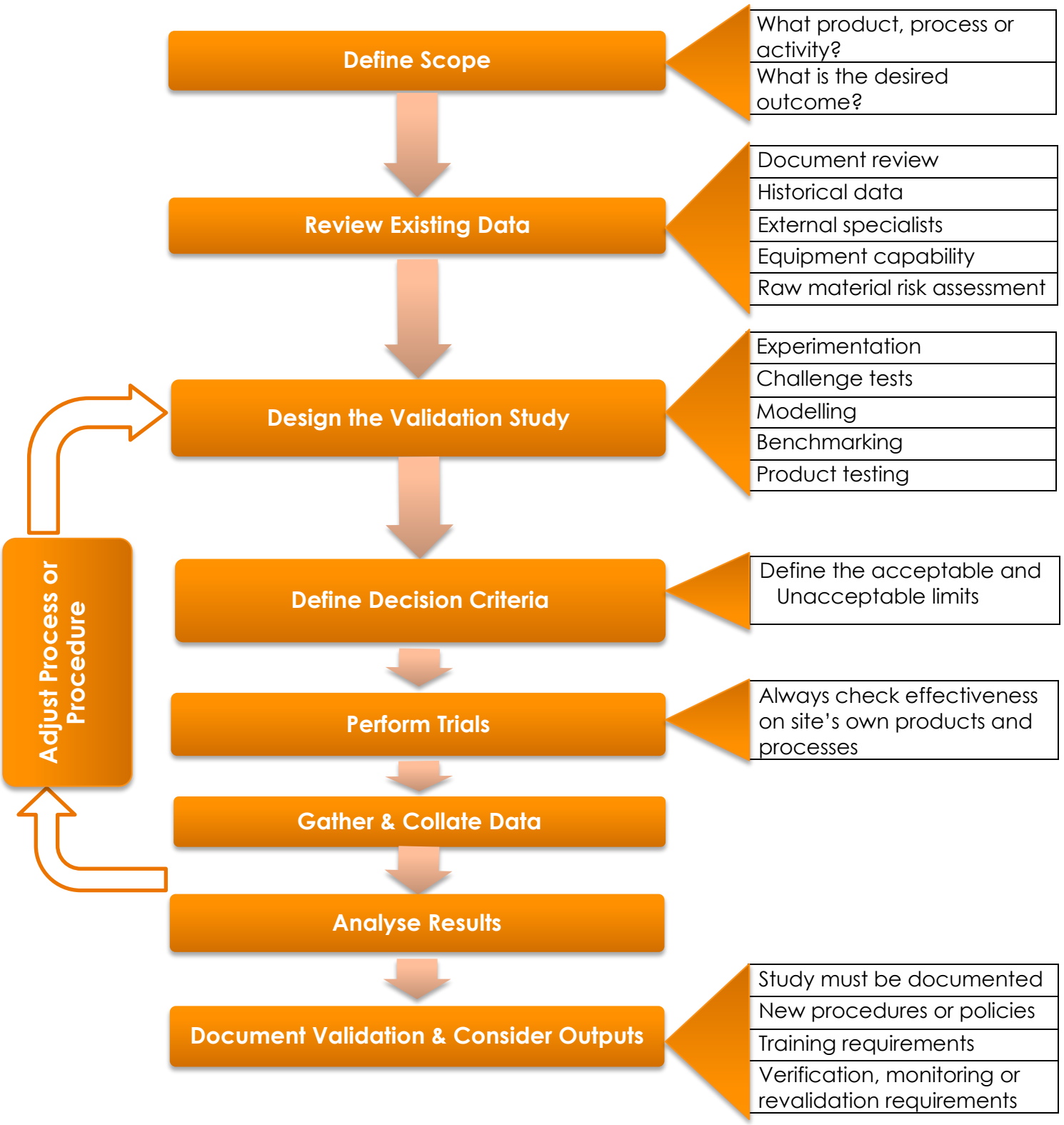
- **Codex:**
  The application of methods, procedures, tests and evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
- **BRCGS Standard**:
  The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended.
  Collection of evidence showing compliance or conformity.

Verification is the on-going activity to determine that the control measures were implemented and effective. The term verification comes from the Latin *verus*, which means truth, and *facere*, which means to make/perform. Thus, verification means to prove that something is *true* or correct Within verification, comparison between the expected result and the obtained result is generally binary (is it met or not true or false).

MONITORING

Monitoring of control measures is the on-going collection of information at the step the control is applied. It focuses on the performance of the control at that specific time or on that specific occasion, i.e. there will be a defined check to a specific parameter. It asks the question 'what is happening at the moment?

VALIDATION FLOW DIAGRAM



DEFINE SCOPE

Identify the controls to be validated – define what you are trying to validate. Be precise - you have to have a proposed plan to try which also means you have to understand the hazard you are trying to manage. For areas like HACCP/ HARA, the site will need to identify the hazard and the proposed control.

REVIEW EXISTING DATA

It will be useful to understand what information is already available. References may include:

- **Document review** - It will be useful to understand what information is already available e.g.
    - Legislation
    - Code of practices (COP)/ Industry guidelines
    - Scientific or technical literature
- **Historical information** - This is applicable when doing a re-validation or amending the product specification when you have well-established operations or technologies from which to draw data.
- **External specialists** - It is important to consider the robustness and competence of any external specialists
- **Equipment capability** - When assessing equipment capability, it is vital to go back to the manufacturer to get advice or data on:
    - Resolution of measuring equipment
    - Suitability of design
    - Positioning of measuring equipment
- **Raw material risk assessment** - Functionality of the raw material is important due to: Customer expectations e.g. 100% vs recycled component; pealable glue vs permanent glue
    - Cross contamination (physical, microbiological or allergenic)
    - Foreign body control
    - Product handling
    - Food safety

DESIGN THE VALIDATION STUDY

This is the most common, and often the most useful step. However care is needed; trials may not be able to be done on the main production line, as failures could mean that current products would be considered unsafe, and you could also contaminate the line. You could carry these out in the development kitchen or pilot plant.

Types of trials include:

Experimentation

Considerations to include the following when conducting experimentation trials:

- **The specification/ design parameter** - Trials/ experiments should be based on a **process design** where the manufacturing conditions, **including operating parameters, processing limits, and components** (e.g. raw material) inputs have been determined.
- **The desired outcome** - Determination of the data to be collected and when and how it will be evaluated e.g. core temperature of products, chemical concentrations, measurement of variables determined during the design stage.
- **The equipment to be used** - Any tests to be performed (in-process, release, characterization) and acceptance criteria for each significant processing step.
- **The sampling plan**, including sampling points, number of samples, and the frequency of sampling for each unit operation and attribute. The number of samples should be adequate to provide sufficient statistical confidence both within a batch and between batches. The confidence level selected can be based on risk analysis as it relates to the particular attribute under examination. Sampling during this stage should be more extensive than is typical during routine production.
- How will **deviations from expected results** be handled i.e. how do you handle it e.g. retest, re-design the experiment
- Consideration for the testing methods and use of approved bodies as certain results require validity as per external organisation guidance.
- Analytical methods used in measuring the process, in-process materials, and the product e.g. use of accredited lab methods to evaluate
- Review and approval of the protocol by appropriate departments and the qualified personnel.'

Challenge testing

A challenge test is a procedure in which a product is challenged by exposure to specified types of hazards. This test hazard e.g. an organism, should be representative of those likely to occur as contaminants.

It is traditionally used in microbiology where a product is inoculated with an organism and then stored as per normal storage of the product, to evaluate whether it will survive and grow.

- **Microbiological** challenge tests also play an important role in the validation of processes that are intended to deliver some degree of lethality against a target organism or group of target organisms where there is an associated performance standard that the process must deliver (for example, a 5 log reduction of Escherichia coli O157:H7 for fermented meats).
- An appropriately designed microbiological challenge test will validate that a specific process is in compliance with the pre-determined performance standard. The design, implementation, and assessment of microbiological challenge studies is a complex task

that depends on factors related to how the product is formulated, manufactured, packaged, distributed, prepared, and consumed.

- Knowledge of the food formulation and history of the food (for example, association with known illness outbreaks and/or evidence of potential growth) is essential when selecting the appropriate challenge pathogens. For example, Clostridium botulinum would be of concern with certain modified atmosphere packaged (MAP) products, and Staphylococcus aureus may be of concern in foods with little competitive microflora and in products with reduced aw .
- Microbiological challenge studies are also useful in determining the potential shelf life of certain refrigerated or ambient-stored foods.

NB:

- Use of real pathogens is inadvisable on food sites due to risk to staff and product; some permitted surrogate micro-organisms have been identified. However, the use of specialist laboratories is recommended.
- Challenge testing can also be used elsewhere, e.g. metal detection (use metal pieces) and laundry – will it remove a known contaminant?

Reference: ('Microbiological Challenge Testing', 2003)'Microbiological Challenge Testing' (2003) Comprehensive Reviews in Food Science and Food Safety. Wiley Online Library, 2(s2), pp. 46–50. doi: 10.1111/j.1541-4337.2003.tb00051.x.

Mathematical Modelling

This is often used, and may include:

- Pathogen growth models – The food industry has over the decades produced huge amounts of data on microbial growth and survival which has allowed the development of prediction tools, i.e. enter data such as food type, pH, etc. and the tools will tell you whether, theoretically ,it could be an issue.
- Thermal process models
- Microbiological risk assessments

Benchmarking

Based on a quality management tool used when comparing one organisation with another on some aspect of performance. A search and analysis of information on various aspects of performance in which another organisation excels with a view to improving own performance.

Sim et al. (2003) defines "a benchmark as a test or set of tests used to compare the performance of alternative tools or techniques." which would include any validation study

When applied in this context it compares processes, practices and performance with similar processes and performance outcomes. It is necessary to clearly define the indicators e.g. markers for success

Reference - Sim, S. E., Easterbrook, S. and Holt, R. C. (2003) 'Using benchmarking to advance research: a challenge to software engineering', 25th International Conference on Software Engineering, 2003. Proceedings., pp. 74–83. doi: 10.1109/ICSE.2003.1201189.

Product testing

If a specific process is being validated then control samples should be collected immediately before the test, and samples collected immediately after the process.

DEFINE DECISION CRITERIA

This is a vital step – we have to determine the he acceptance criteria; 'pass mark' for what is acceptable determination of what is unacceptable? The acceptance criteria should be practical, achievable and verifiable. In some situations, this may legislative, e.g. limit on heavy metals or listeria in a ready to eat product, but sometimes it could be determined by customer or industry demands.

PERFORM TRIALS

This is particularly important for testing – ideally multiple tests from multiple productions. There is no set number of replicates for a validation study. Many data sources will recommend a minimum of 3 replicates which is acceptable for many situations, but the more the better, and in some circumstances many more. Generally, the more tests the better, but a number of factors will influence choice:

- Timescales – how long it takes to get the results, e.g. compare testing the metal detector with laboratory testing of multiple production batches.
- Variability of process/raw materials.

GATHER & COLLATE DATA

Depending on what hazards you are trying eliminate/ reduce will determine the type of data you gather and hence the test methods.

- Products can be tested to determine if specified criteria is met e.g. absence of a target organism, or a defined acceptable level of contamination with specified organism.
- Validations involving allergens commonly include product testing to determine presence or absence (detectable limits) of specified allergen.

- Active product ingredient tests against defined pharmaceutical standards (relevant for manufacturers of food supplements and pharmaceutical products)
- Chemical Tests in accordance with protocols for target substance.
- Visual inspection may be appropriate for physical hazards

ANALYSE RESULTS

Analyse results against the acceptance criteria. The analytical methods should be sure that the lab has the relevant applicable and official methods of analysis i.e. the lab can detect your defined limits of detectability.

DOCUMENT VALIDATION & CONSIDER OUTPUTS

Documentation is important so that knowledge gained about a product and process is accessible and understood by interested parties.

Consider outputs i.e. what needs to be done to ensure that the required level of operation, proven by the validation study to be an appropriate control, is done on a routine basis e.g. training, standard operation procedure

WORK-BASED VALIDATION & VERIFICATION COURSE ASSIGNMENT

PURPOSE

To assess the application of validation & verification principles in the workplace as follows:

- Demonstrate understanding of validation and verification through completing a validation or revalidation study and proposing appropriate verification activities.
- Show clear understanding of information required to complete the study and choose appropriate experimental design for the study.
- Complete a report to demonstrate understanding of BRCGS requirements for documentation of validation and verification

DELEGATE ASSIGNMENT OVERVIEW

Consider a production process control, prerequisite programme requiring validation, critical control point (CCP), new product development or other area specified in a BRCGS Standard applicable to your operation requiring validation within your site or that has been previously validated. Answer the following:

- How would you validate your chosen process or re- validate an existing process if a change occurs? (50%)
- How would you subsequently verify the process is operating correctly? (50%)

In both cases please ensure that the answer contains specific information that relates to the process you have selected.

DETAILED ASSESSMENT BRIEF AND CRITERIA

For both parts of the answer the delegate should provide examples that are relevant to the specific process selected, rather than regurgitating general examples that were discussed during the training.

VALIDATION

Define scope

- A brief overview of the subject of the study e.g. production process control, prerequisite programme, validation, critical control point (CCP) and new product development.
- This should be sufficiently detailed to provide adequate background information for the trainer.

Review existing data

- Most important here is historical data – if the process has been running for some time there should be an old validation study, verification data and monitoring results all for which can input to the revalidation.
- Delegate is to demonstrate the ability to complete a document review using appropriate sources e.g. codes of practice, Industry guidelines, scientific or other technical literature, raw material or equipment suppliers.
- If it is new product development, details of the new product should be given. The site should consider the significant differences/challenges associated with the new product as this will be a guide for the content of the validation study

Design study

- What would the site do and why? This should include some form of experiment design, but the type of experiment (e.g. challenge testing, modelling, benchmarking product tests) will depend on the specific process selected
- Delegate must identify an appropriate test, trial or challenge.

Define acceptable/unacceptable

- The delegate should indicate pass/fail criteria which will be dependent on what the process is trying to achieve
- Some processes will have multiple action limits, for example, heat treatment of food products involves both a time and temperature

Perform trials

- Delegate should reference the need for multiple or replicate tests rather than performing the test/trial just once

Gather & collate data, document and analyse results

- The delegate should give an indication of what they would do with the data

Review and document conclusions/outputs

- There should be some form of output from a validation study e.g. acceptance and introduction of new process or change of parameters followed by a new validation study

VERIFICATION

Method (or Methods) used

- Answers could include any suitable process highlighted in the training. For example, inclusion in internal audit programme, trend analysis or a schedule of product/process testing

- The method(s) used should not confuse verification with monitoring of a production parameter

Frequency

- Verification is an ongoing process, so there should be a frequency or schedule for verification activities
- Frequency should be based on risk (i.e. a critical parameter (e.g. a CCP) is monitored continuously and verified frequently, whereas an important, but less critical parameter may require less frequent verification assessments)

Critical Limit (or Action Limit)

- There should be a pass/fail criterial such that the site knows when the process is not effectively, delivering the required level of operation i.e. does the site know when the process fails the verification assessment.

RESOURCES

Course content references

Global Harmonization Task Force - *Quality Management Systems - Process Validation Guidance* (GHTF/SG3/N99-10:2004 (Edition 2) page 3

(CAC/ GL 69 – 2008)

Mail online, published: 10:53, 11 June 2012

('Microbiological Challenge Testing', 2003)'Microbiological Challenge Testing' (2003) Comprehensive Reviews in Food Science and Food Safety. Wiley Online Library, 2(s2), pp. 46–50. doi: 10.1111/j.1541-4337.2003.tb00051.x.

Sim, S. E., Easterbrook, S. and Holt, R. C. (2003) 'Using benchmarking to advance research: a challenge to software engineering', 25th International Conference on Software Engineering, 2003. Proceedings., pp. 74–83. doi: 10.1109/ICSE.2003.1201189.

WHO Technical Report Series, No. 937, 2006 , Annex 4 - Supplementary Guidelines on Good Manufacturing Practices: Validation

U.S. Department of Health and Human Services , Food and Drug Administration,(2011) 'Guidance for Industry Process Validation : General Principles and Practices.

WHO Technical Report Series, No. 937, 2006 , Annex 4 - Supplementary Guidelines on Good Manufacturing Practices: Validation

System Verification. (2015, June 16). SEBoK, . Retrieved 12:49, April 24, 2018 from http://www.sebokwiki.org/w/index.php?title=System_Verification&oldid=50858

Material from Reference: System Verification. (2015, June 16). SEBoK, . Retrieved 12:49, April 24, 2018 from http://www.sebokwiki.org/w/index.php?title=System_Verification&oldid=50858

ACKNOWLEDGEMENTS

BRCGS is grateful to the experienced auditors, trainers and manufacturing staff who give advice, guidance and feedback, in addition to writing and reviewing training exercises and assessments. We acknowledge the following, who are listed below:

Tayo Irawo	Food Safety & QMS Consultant & Trainer
Lori Carlson	Technical Writer and Food Safety Consultant
John Husband	Totrain

You can view the Global Standards, as well as Interpretation Guidelines, supporting publications and additional resources quickly and easily via BRCGS Participate, our online subscription platform. BRCGS Participate is an innovative and powerful online management system that gives you immediate access to all the documents relevant to a particular Standard, linking them clause by clause. To find out more and to subscribe, visit BRCGS Participate.

Printed copies and PDF downloads of the Global Standards, Interpretation Guidelines and other publications can still be purchased from the BRCGS Bookshop, with all Global Standards now available to download free of charge.

BRCGS Professional is a learning programme which will give you international recognition for the key skills and knowledge essential for product safety management.

www.brcgs.com

CHICAGO • LONDON • NEW DELHI • SHANGHAI • TORONTO