Position Paper on Process Validation for the Laundry Industry -2013-

representing textile care professionals

Position Paper on Process Validation for the Laundry Industry

Definition of Validation and Development of Protocols for Achieving It

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Background

The industry standards for biocontamination control in laundering are CFPP01-04 and BS EN 14065 (RABC). The former replaces the prescriptive guidance document HSG(95)18 and offers both a prescriptive protocol (to suit NHS organisational and operational structures), but also the option of the RABC approach to laundries which are certified to BS EN 14065 for the healthcare sector. It also allows for the development of alternative decontamination processes to thermal disinfection. In practice, both documents have wider application than the healthcare sector alone since the major benefit offered by the Laundry Industry, and greatly appreciated by its customers, is the hygienic cleanliness afforded by disinfection.

RABC was developed as a technical quality management system for controlling biocontamination (and recontamination) of textiles where hygienic cleanliness was a priority for rental service customers. Its authors concentrated on hazard & risk analysis and process monitoring as the guiding principles.

They did recognise that process validation was **the** major contributor to product quality assurance. Inherent in this procedure is the principle of parametric release. This means that the key process variables for controlling product quality are monitored in real time and must be observed to meet specific values before the product can be released to the next stage or to the customer. This is especially necessary where product quality control methods are impracticable because of the unacceptable delay (logistics, commercial imperatives etc.) in producing test results prior to release of the product for use.

Assured quality by validated process control, in concept and practice, is not new and is the basis, for example, for pharmaceutical and much food production where parametric release is essential. For the reader who wishes to know more or seeks to be convinced of the necessity for the approach, the bibliography, included at the end, gives examples of the detailed technical treatments specifically developed for these industries.

Though BS EN 14065 does not specifically define validation, it makes it a requirement and is a necessary step in providing tolerance, alert and alarm values for key process variables, evidential identification of which is also a requirement of the standard (clause **6.2.6.1 Validation and revalidation of the laundry process*** of BS EN 14065). Unfortunately the current version of BS EN 14065 gives no proper indication of what validation is or to how it should be achieved.

* **6.2.6.1 Validation and revalidation of the laundry process**

The process shall be designed to achieve an agreed level of microbiological quality and shall be validated. This shall be carried out according to the process specification and using specific microbiological test methods.

The validation is carried out to assure that the process complies with the required performance and to establish the limits of identified process parameters to allow product release without routine testing of textiles.

Perhaps this is less surprising when one realises that when the standard was developed the delegates were from EU countries which had long ago established and implemented thermal disinfection principles for assuring the microbial quality of textiles. Even though there was no common agreement on the exact conditions, it was generally accepted that the time temperature relationship was important and the process should involve immersion of the textile (attention to load weight, water level etc.) Heat was the principle disinfecting agent for micro-organism kill and, provided a homogeneous level in the machine, liquor and work could be maintained, kill was assured. It remains a relatively simple technical task to determine this in real time with thermocouples and/or sealed electronic monitoring devices which can be processed with the load.

Now, however, the status quo is being challenged by innovative low temperature disinfecting processes, developed in response to the need to reduce energy use. Since there is no large body of evidence to support the consistent reliability of such processing, it is necessary to properly examine what process validation really requires and what principles need to be addressed in order to justify conversion to these processes where hygienic cleanliness is critical.

Validation

Since validation involves more than solely attention to the process, it may be useful to describe the whole concept before concentrating on process validation

Other industries have adopted an approach based on EU GMP Guidance for Pharmaceutical and Cosmetics Manufacturers. This is similar to FDA guidance (see Bibliography for references). This approach is proven worldwide and allows the suppliers and laundry management to control the scope and methods of validation, in line with the market requirements, the risk profile of the goods being processed and the capability of the processes being used.

The EU/FDA validation model, often referred to as “life cycle” or “DQ/IQ/OQ/PQ” uses the term validation globally, i.e. proof of process capability at every stage of its life cycle, and at regular intervals while in use. Figure 1 shows how the pieces of this model fit together. To meet it, manufacturers, suppliers and launderers will need to co-operate in order to work through the validation model.

<table>
<tr><th>Location</th><th colspan="3">Validation “life cycle” stages</th><th>Primary Responsibility</th></tr>
<tr><td>Manufacturer /supplier</td><td colspan="3">Design Qualification (DQ)</td><td rowspan="2">Manufacturer/supplier</td></tr>
<tr><td rowspan="4">Laundry</td><td rowspan="3">Process Qualifications</td><td rowspan="2">New set up Equipment &/or Programmes</td><td>Installation qualification (IQ)</td></tr>
<tr><td>Operational qualification (OQ)</td></tr>
<tr><td colspan="2">Established set up - Performance qualification (PQ)</td><td rowspan="3">Laundry/ RABC Team</td></tr>
<tr><td colspan="3">Routine monitoring (verification that supports validation)</td></tr>
<tr><td colspan="3">Re-validation (PQ), annual or as indicated by results, change dependant</td></tr>
</table>

Figure1 Diagram of the ‘Life Cycle’ Model for Validation

Key terms:

Design Qualification (DQ)
The manufacturer/supplier (e.g. of washing equipment, detergents) should establish and document intended performance levels and physical requirements to achieve these levels.

Installation/Operational Qualification (IQ)/(OQ)
The manufacturer/supplier, with the laundry, should ensure that all equipment and related systems are assembled, installed and operate as intended, e.g. motors , utilities, indicators and controls function as intended.

Performance Qualification (PQ)
Laundry management, through an RABC team in the case of BS EN 14065, should design and execute challenges intended to establish that existing processes are effective and reproducible. The alternative name for this stage is Process Validation

Re-validation
This step normally consists of a repeat of the PQ, perhaps with some modification based on previous experience and taking into account and documenting any interim variation in the process.

Process Validation

Process validation needs a definition so that all may have the same understanding of what it is, especially since it is the essential step in assuring quality of the product. However attempts to define it usually result in complicated sentence structures and provisos which make the definition incomprehensible to anybody not familiar with it in the first place. It is probably more useful to describe the important parts of process validation and to then develop these into a definition.

The first statement about validation is that the intention is to prove that a process produces the product with the desired attributes, time after time.

The second statement about validation is that a practical investigation into the process is required (let's restrict this to the wash process for now).

We also need to agree some terms to help us describe the experimental work of the investigation:

Independent variables – these are the process variables like time, temperature, load weight, dip, pH, alkalinity which can be specified for a particular wash process i.e. the variables which the launderer can control.

Dependent variables – these are the outcomes of the wash process such as whiteness, stain removal, bug kill, chemical damage. They are dependent on the values set for the independent variables. They are also known as response variables or simply as responses.

The third statement about validation is that BS EN 14065 requires the identification of the independent variables or key process indicators which control the response we must achieve to satisfy the customer

The fourth statement about validation is that BS EN 14065 requires tolerances (precision) to be set on the independent variables so that the response stays within specification, even if the independent variable drifts a little from its set point.

It therefore follows in a **fifth statement** about validation that we need to use it, not just to identify but to quantify the effect of individual independent variables on the responses – or how else could we otherwise estimate their tolerances?

One way that these objectives can be realised for validation is through a planned investigation which systematically varies the independent variables over realistic ranges and measures the corresponding responses. Appropriate analysis of this data will then allow the significance of the independent variables and their contributions to be calculated and allow proper tolerance to be set..

That's all very well, but who is to do this type of specialist technical investigation? It is too much to expect that laundries should possess the capability to do it and in any case the busy production environment of a laundry is not the appropriate place to carry out such careful and exacting work. Certainly in the case of innovative processes it is the responsibility of the supplier to investigate thoroughly their processes and generate sufficient data to provide the launderer with a good starting point for a simplified validation procedure more suitable for the laundry environment. Methodology for this is discussed in the next section and more detailed information is provided in the appendices.

Examples of definitions of validation

The following are drawn from various sources including ISO 9000 series and are intended to convey the meaning whilst still trying to keep it simple. Given the foregoing discussion they achieve neither successfully!

- Confirmation, through objective evidence, of the key variables required to control a process so that it can deliver an agreed product quality.

- Establishing documented evidence which provides a high degree of assurance that a specified process will consistently produce a product meeting its predetermined specifications and quality attributes.

TSA proposal for a definition for use with BS EN 14065

Process validation: The planned investigation of a process in order to quantify the effects of significant key process variables on textile microbial quality, set tolerances and ensure a repeatable result against a pre-determined specification.

Approaches to Process Validation

When approaching process validation as part of certification for BS EN 14065 it should be kept in mind that the standard is a Quality Management System and that at its centre is a Quality Manual or technical file. Evidence of process validation is fundamental to the system because it underpins the principle of quality assurance.

Process monitoring

By now it should be clear that process validation is a rather different activity from process monitoring. The latter is simply the measuring and the recording of independent variable and response values and, whilst very important, doesn't of itself provide insights into how the process works or how to control it.

Empirical data from an historical database

In the case of thermal disinfection processes, time-temperature data and microbial quality of finished work collected over a significant period of time may be used to demonstrate the stability of operation of the plant equipment, procedures and activities if they correlate well. It is reasonable to assume that over long periods of operation the key process variable, though not formally identified have been subject to 'natural drift', and the plant is unlikely to suddenly begin to operate in a markedly different way. It is likely that laundries which have this information will have been operating close to the requirements of BS EN 14065 for a significant length of time.

This database should be formalised and incorporated into the Quality Manual in a way that allows management to demonstrate its understanding of the effect of operating procedures and independent process variables (e.g. in washing) on the microbial quality of the product and can have confidence in the alert and action limits which have been set to control the process.

This circumstantial approach is heavily protected by the known time-temperature relationship for thermal disinfection and the principle of real time monitoring and parametric release – provided subsidiary key process indicators mentioned previously have been respected.

Thorough technical investigation of innovative processes

Where new, innovative processes are to be offered, or where little historical data is available, a high level of technically disciplined investigation is required to provide evidence for the RABC Quality Manual. It is a reasonable expectation that suppliers should have a thorough technical understanding of their processes and be able to provide sufficient technical detail to customers to allow them to both carry out the validation requirements of BS EN 14065 in an appropriate form within the laundry environment (see the section on *Worst case challenge* below) and provide evidence for the Quality Manual.

Experimental Design

Statistical experimental design is a technique which few manufacturers and suppliers in the Laundry Industry will have any knowledge or experience of at the present time. Nevertheless it is a technique which is gaining prominence in other industries where process validation is essential, and this includes customers of textile rental companies. It offers a very cost-effective approach for the development of innovative processes and has the considerable advantage of leading automatically to a realisation of the five validation statements mentioned above. It provides a high standard of evidence for the BS EN 14065 Quality Manual. It is to be highly recommended as a skill to be acquired by those offering innovation to the market.

In the experimental design approach all the independent process variables which experience indicates will contribute to the required response are varied according to a statistically-based experimental plan. This approach is potentially the most powerful available, identifying and ranking the significance of variables, revealing otherwise undetected process variable interactions, providing guidance for future process development and allowing confident calculation of safety margins (tolerances) for key variables to sustain the intended result.

A brief introduction to the subject is given in Appendix A

A further advantage for this methodology is that it can go a long way in making up for the absence of parametric release criteria.

Alternative offers

i) Traditional investigation – inefficient as an investigational approach for learning about an innovative process, easy to miss important process variable interactions, inaccurate for predicting the quantitative effects of variables and tolerances.

ii) Simulation tests - an alternative approach is to demonstrate the efficacy of the disinfecting agent in an approved test method which simulates the conditions in which it will be used and to then provide the launderer with a set of minimum machine and process settings arrived at by the supplier.

These alternatives may have a place in general laundering where decontamination may not be so critical, but the application to CFPP01-04 is not straight forward.

In our view:

a) If all the precautionary requirements mentioned in CFPP01-04 are met then this approach could meet the basic Essential Quality Requirements (EQR) set by CFPP01-04.

b) However, if the BS EN 14065 route to CFPP01-04 compliance and Best Practice is chosen this approach does not allow compliance with BS EN 14065 (clause 6.2.6.1*) because of the following limitations.

i) The approved test method serves to demonstrate the potential of the disinfecting agent; it is not a validation of process as carried out in the laundry.
ii) A simple statement of the minimum wash settings is insufficient evidence for the Quality Manual.
iii) It leaves the launderer with the decision as to whether the minimum settings will be sufficient for the level of soiling in the load.

iv) Alternatively, the launderer has to increase the settings to 'make sure' the load is properly processed – with no means of realistically checking this and leading to the possible consequences described in the following paragraphs.

v) Parametric release may not be possible because an effective method for real time monitoring of the usage of the disinfecting agent may not be available. In consequence a non-compliant load could not be safely identified and quality assurance of the product would be jeopardized.

Some experts in the DoH sphere have serious doubts about whether low temperature, chemical disinfection is a validatable process i.e. one which a) can be controlled effectively for a number of required responses e.g. microbial quality, textile life b) can deliver microbial quality to the required level in all circumstances e.g. whatever soiling is present in the load and c) parametrically release compliant loads or conversely, detect non-compliant loads in time to isolate and reprocess them.

For example, one of the potential problems involves the fate of chemical which is introduced into the process for the purpose of disinfecting work. Most are highly reactive oxidising agents which will react with many other things than solely the micro-organisms present e.g. the machine, the textiles, soil, stains, detergent, other wash chemicals present. So even with perfect monitoring of dosing equipment functionality, dosing rate, movement of chemical into the machine not all the chemical will be available to kill micro-organisms. Equally it is unacceptable to dose with high levels in the hope of ensuring kill because of probable damage to the machine and textiles and, of course, the excess chemical cost this would incur. The DoH argument will invoke the need to introduce some form of real time monitoring analogous to thermal disinfection with respect to heat and temperature. It is uncertain that real time monitoring of chemical species in the dynamic environment of a washing machine is technically reliable enough at present.

However the availability of statistically supported objective evidence and reliably calculated tolerances would go a long way to addressing this otherwise technically difficult challenge.

Worst case challenge

The worst case challenge approach is particularly useful where no large historical database exists and, by inference, for innovative processes. It has been developed in the EU & FDA guidance as the most cost effective and practical way for industry- (laundry-) based validation. It combines local experience, equipment and methods with the detailed knowledge gained by suppliers as a result of their own structured investigations (see previous section and Appendix A). The process validation, or PQ, is planned with extra constraints to present a scenario that is as tough a challenge as could be expected.

For example a wash process PQ could be designed with reduced time, temperature and dip, increased load weight and test pieces could be inoculated with spore-forming organisms that are more difficult to inactivate or remove from the linen (see section below on bio-monitoring).

Whilst launderers could guess at a 5 or 10% change in a variable, it would be far more robust if the supplier provided data confirming the statistically significant independent process variables and their estimated tolerances for sustaining the required response (bug kill etc.) so that in-plant investigations could be carried out near, but within, the tolerances with savings in production time and money. But why should the launderer need to do anything if the supplier has already provided detailed technical evidence? The answer is that circumstances alter cases and different equipment, operating methods and even textiles can make small, but significant changes.

Worst case challenge tests need to be conducted multiple times until it has been established with reasonable confidence that the process delivers the desired results in a repeatable way.

More information on process validation in laundries and the design and implementation of PQs can be found in reference 5 of the Bibliography.

Biological Assay Methods to Determine Log Kill

All of the biological assay methods can be criticized for one reason or another so that it is probably better practice not to rely on one method, but to employ a combination. Some points to consider are given below:

A sealed tube of cultured bacteria may be used to determine the level of thermal disinfection since it is only affected by heat. Use in a low temperature process will demonstrate the reliance on the chemical disinfection.

A fabric swatch inoculated with cultured bacteria and tagged onto a piece of linen will be susceptible to heat, chemical and mechanical action. It may be thought that this is the most realistic, but there is the chance that bugs may not be killed but simply washed off and re-deposited in the rest of the load. To some extent this effect can be assessed by including *sterile swatches* and carrying out the monitoring in 'normal loads i.e. loads of used work at the process classification being assessed. This will ensure that a typical bio-burden is being assessed and if the sterile swatches pick up viable organisms that dilution in the load (rather than by the wash liquor is playing a part.

A **"***biological indicator***"** (swatch inoculated at a known concentration and contained in a semi permeable membrane) is potentially the most appropriate as it allows the chemicals and heat to contact the bacteria, but prevents the bacteria from being rinsed away. There is a concern that when these indicators are produced commercially the inoculated swatch is doped with substances to promote shelf life and these may have a protective effect, especially in less challenging wash processes. In addition it has been pointed out that the pore-size of the semi-permeable membrane is critical. Whilst retaining bugs it may also exclude larger molecules such as detergents which have a role to play in bug kill.

ATP assay method detects ATP, a chemical released from dead or living bacteria present. Thus absence of ATP infers absence of bacteria, living or dead, and not categorically that all have been killed. Presence of ATP could mean chemical from dead bacteria, or a mixture of dead and living organisms. Nevertheless it can be a useful indicator method for looking at solid surfaces in sensitive areas of the laundry and it also some organisms release toxic chemicals when they are killed.

Targets for Log Kill?

The generally accepted level of satisfactory kill is log 5 for vegetative bacteria and log 4 for spore formers, though in some jurisdictions log 6 or even log 7 are being proposed for the former.

Selection of organisms

There is no industry standard for the types of organisms which should be used for inoculated swatches. Care needs to be taken in the selection of indicator organisms a) so that they are safe for those who may come in contact with them at whatever stage and b) that they reflect the organisms likely to be on the used work.

Likely key process variables

A comprehensive list of KPIs can be found in Annex C of EN 13569 cabinet roller towels – performance requirements and processing. Some of these independent variables and their importance are discussed below

Temperature High correlation with bug kill, above a threshold temperature which will be organism dependent to some degree. Easy to measure and can therefore form a part of a parametric release if required.

Time High correlation with bug kill, especially as temperature decreases. Also one of the primary variables needed for parametric release. Need to stress the significance of "**mixing time**" because it is very important for assured disinfection for the temperature – time relationship to be established in the load.
It may be of even greater significance for chemical disinfection, where the concentration of disinfecting (oxidising) agent can be reduced by reaction in the wash liquor before ever it comes into contact with the linen or bugs held on it. Sewing biological indicators into pockets of heavy cotton rich garments might provide a worst case scenario!

Water Volume/Dip This will be machine specific and affects a) the assumption that thermal disinfection is an immersion process b) the concentration of the disinfecting chemical and c) the mechanical action of the process. Water loss from the drum through leaking drain valves is common source of error and will affect processes relying on the indirect measurement of chemical activity in the wash and the mechanical action. Note that many machines will add water to maintain a dip, and that this will reduce chemical concentration.

Disinfecting Chemical Concentration This will clearly be the primary variable affecting disinfection in a chemical disinfection process. In principal the concentration can be determined from the volume of chemical and water added to the drum, at least for liquid or solid additions, but as discussed above this is an indirect method and prone to error. (For gaseous additions pressure, flow rate and dissolution rates at prevailing conditions may be significant). Additionally, it is expected that the chemical will react with the load and that the concentration will fall through the process. Real time monitoring of chemical concentration would allow the concentration to be maintained by the addition of more chemical as the concentration falls, or at the very least confirmation that the concentration was always above a minimum level which falls within the sensitivity band. In an ideal world this should be directly monitored, but practically this is very difficult. Work on detection using chemical bond excitation frequencies (in particular UV) holds the prospect of in line measurement.

Other Wash Chemistry The interaction with any other chemicals used in the wash process will need to be addressed. Alternatively, the disinfecting chemical could be used in a part of the process when there are no other chemicals present (1^{st} or 2^{nd} rinse), but chemical carry over into this section would need to be considered.

Chemical composition of the water pH, hardness, iron content etc. of the raw water will need to be considered to determine possible interaction with the disinfectant.

Mechanical Action (MA) This is not a truly independent variable, but is derived from others such as drum configuration (diameter, number and size of beaters etc.), dip level, drum rotational speed and degree of loading – all of which affect the type of MA (rubbing/compression) and thus on mixing (chemicals and heat).

Does low temperature washing necessarily make for energy savings?

As revealed at the TSC Forum in October 2012 machinery and chemical suppliers are divided over whether energy savings accrue from washing at lower temperature. Before investing in the expectation of making a significant contribution to the CCA2 energy reduction target, as well as the increased effort to validate decontamination processes, launderers need to consider the options carefully.

At the Forum speakers for both Jensen and Christeyns, using calculations based on more traditional CTW operation with and without heat recovery demonstrated how reducing wash temperature could result in inefficiencies elsewhere and that the estimations of energy (and cost) savings could be confounded if seasonal variations (degree days) were not taken into account.

Jensen estimated that the direct steam costs for 75C & 40C, with and without heat exchange (HE) were in the rankings shown in the following table.

Temperature/heat recovery	Ranking of running costs , 1 = cheapest	
		Including extra evaporation costs for processing at 40C
75C, without integrated HE	4	3
75 C, with integrated HE	1=*	1
40C, without integrated HE	3	4
40C, with integrated HE	1=*	2

*75C ever so slightly more expensive

Christeyns, quoting from a case study, showed how potential savings could be swallowed up by additional chemical costs to compensate for the lower wash temperature and how clever wash process design could save water, and thereby, energy.

Ecolab countered by showing how, after low temperature washing, temperature in the rinse section could be raised using heat recovered from elsewhere in the laundry thereby retaining dewatering advantages. This potentially meant that, after initial start-up, little or no ‘heat’ needed to be supplied directly to the forward and middle compartments, allowing longer reaction times with purpose designed low temperature wash chemicals. Other benefits of increased production rate and textile life were also claimed.

The processors in the Forum audience had clearly been giving considerable thought to this topic and made the following points in the subsequent discussion session:

a) Lowering of temperature could not be entirely compensated for by chemistry and time for all soiling – processors would need to be selective about which soiling classifications could be processed this way.

b) There were issues to be addressed for the validation of decontamination processes. The requirement was for an assured process and many had difficulty understanding how this could be achieved when control of soiling types and levels was such a blunt instrument. The need for in-line chemical concentration monitoring was very apparent.

c) There would be additional equipment and infrastructure costs associated with a switch to low temperature, especially if heat was to be won from less traditional parts of the laundry.

d) Launderers would need quality, independent advice specific to their sites to assist them in decision making.

Appendix A Process Validation using Experimental Design

(Only to be read by those NOT suffering from a nervous disposition)
The so-called traditional experimental method – change one variable at a time – is wasteful of information and rarely produces results which are amenable to statistical analysis and predictive use.

By contrast statistical experimental design techniques based on factorial or fully crossed designs are far more efficient and effective for investigating, developing and ultimately validating a process. A properly designed experiment will confirm whether all the significant independent variables (and possible interactions) have been accounted for, what their individual contributions to the response are and provide a predictive model for the process.

Experimental design is a complete topic in itself. Whilst it provides many techniques for reducing the size and cost of complex investigations, it also requires an experienced experimenter. However the following may serve as a simple example of its power and what it can achieve. Independent variables (A, B & C) are assigned two values equidistant, but within a realistic range, of their typical values. All combinations are then run and the response (or responses) is measured. Thus for three variables at two values (or levels) of each there will be 2^3 or 8 combinations (or treatments) in the experiment and 8 measurements for each response.

The design (matrix) and results (vector) might look like this

Run	A	B	C		R
1	-	-	-		248
2	+	-	-		280
3	-	+	-		236
4	+	+	-		264
5	-	-	+		232
6	+	-	+		272
7	-	+	+		256
8	+	+	+		284

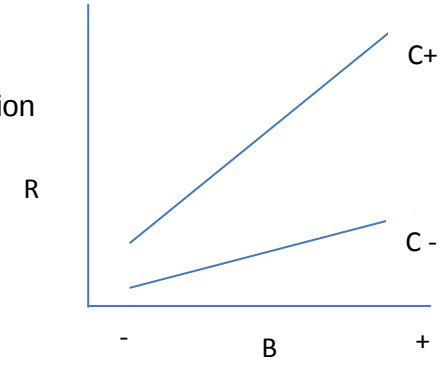
Where the - & + indicate the lower and higher values of each independent variable A, B & C and column R contains the responses measure during the run..

In reality there is more that can be done with this example, but it is beyond the scope of this document. The 'best fit' or (linear regression) analysis (carried out using the stats package on Excel) yielded an equation of the form

$$R = 259 + 16A + 8BC - 2AB + 2C \qquad \text{Fit} = 93\%$$

AB and BC signify interactions between A & B and B & C which traditional methods would have missed. This just means that the way changes in B affect R is influence by the level of C - graphically this looks like:

Diagram showing the interaction between B & C

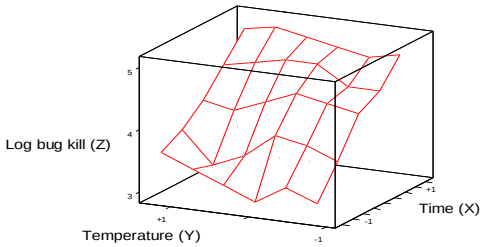


The percentage fit refers to the values of R calculated from the equation compared to those measure in the experiment. At 93% this would suggest that the investigators had accounted for most of the variation in R and it would be very unlikely that there was another significant independent variable that they had missed.

The coefficients in the equation reveal the magnitude of the importance of the variables thus A (16) has twice the effect of interaction BC (8) which in turn has 4 times the effect of C (2). Interaction AB has much the same magnitude of effect on R, but is negative and so will reduce its value, whilst all the other terms in the equation are positive and will act to increase R.

The equation can be used to calculate tolerance levels for each of the variables by substituting in different values and seeing how R is affected. This is the meaning of tolerance within the context of BS EN 14065. It should not be confused with the precision or calibration of instruments or devices used to monitor the key process variables.

In turn these equations can be represented graphically (see example below) and usefully reveal regions of the so-called response surface where R might change little with changing process variables – and be described as a robust process.



A graphical representation of the model equation. The 3-D graph is called as a response surface

Thus this methodology allows full compliance with the requirements within BS EN 14065.

Appendix B Certification to BS EN 14065

To become certified to BS EN 14065 a launderer first needs to purchase and implement the Quality Management System and specific requirements of the standard. BS EN 14065 (or RABC as it is often referred to) was written as a stand-alone system, but also so it could readily be included alongside the ISO 9000 series. In addition, TSA has published a document 'TSA Guide on the implementation of BS EN 14065' (reference 5 in the Bibliography) to assist. The implementation will involve commitment, effort and cost and is not a light undertaking. However, those who have achieved it not only comply with Best Practice for CFPP01-04, but report significantly improved operation of the business and markedly improved staff performance and attitude because of increased training, responsibility and involvement.

In the later stages of implementation, or on its completion, the company will wish to be evaluated for certification. Anything or anyone can be evaluated - products, equipment, people, management systems or organizations – and by anyone. However there is little to be gained from evaluation by an organization whose quality management system has not been accredited to a higher level than the one it is certifying.

What is Accreditation and Certification?

The UK Accreditation Service (UKAS) is the sole Government-recognized accreditation service for this country. It provides a formal, third party recognition of competence to enable identification, and selection by informed choice, of a proven, competent evaluator. UKAS accreditation allows the evaluator to demonstrate to its customers that its own quality management system has successfully met the requirements of international accreditation standards. UKAS offers accreditation to laboratories, test house, equipment & instrument calibration services and certification bodies.

UKAS accredited-certification bodies will be recognized by textile rental customers and their auditors as being competent, impartial and of a high standard.

Examples of UKAS accredited organizations include BSI, SGS and Intertek. NSAI in Ireland is accredited by the Irish National Accreditation Board, INAB (equivalent to UKAS).

Note: Each certification body is accredited by UKAS for a number of specific standards, which are sometimes referred to as its schedule. UKAS charge for accreditation on a per standard basis, and the fees can be quite significant. The certification body must decide whether it is commercially viable for it to include a standard on its schedule i.e. whether it can achieve sufficient return through certification fees from customers to justify the cost of accreditation. It is understood that currently this may not be the case in UK for BS EN 14065 because the demand is relatively small, but that certification may still be offered on the basis that the evaluation will be carried out under the same quality management system as applies for the standards which the certification body is accredited for.

Bibliography

Reference	Description
1. EU Guide to GMP for medicinal products	Analogous to HACCP for food sector, often more detailed and prescriptive. Particularly relevant for guidance on validation (Annex 15 – Qualification and validation). Available online at: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4_en.htm
2. FDA Guideline on General Principles of Process Validation	Developed for the pharmaceutical and medicinal sectors as a model for greater assuring product safety. Predecessor to EU GMP guidance and prime reference for validation text in this document. Available online at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.h*tm*
3. Global Harmonisation Task Force (GHTF) Quality Management System – Process Validation Guide 2004	Produced by the GHTF, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development. http://www.ghtf.org/documents/sg3/sg3_fd_n99-10_edition2.pdf
4. Pharmaceutical Inspection Convention Validation Master Plan PI 006-3 2007	This document comprises individual Recommendations on four topics relating to Equipment Qualification and Process Validation in pharmaceutical manufacture, as follows: Validation Master Plan; Installation and Operational Qualification; Non-Sterile Process Validation; Cleaning Validation http://www.picscheme.org/publication.php?id=8
5. TSA Guide on the implementation of BS EN 14065	This document must be read in conjunction with BS EN 14065. It discusses broader issues not directly dealt with in the standard, provides advice on solutions and a structured approach to implementation. It also addresses deficiencies in the standard such as direction on validation. http://www.tsa-uk.org
6. EN13569	Cabinet roller towels – performance requirements and processing