Disinfectant Efficacy Testing

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<1072> Disinfectants and Antiseptics

SELECTING A DISINFECTANT FOR USE IN A PHARMACEUTICAL MANUFACTURING ENVIRONMENT

"When selecting a disinfectant for use in a pharmaceutical manufacturing area, the following points should be considered: ***number and types of microorganisms to be controlled;*** *the* ***spectrum of activity of commercially available disinfectants****; the* ***claims*** *as a sterilant; the disinfectant or sanitizer supported by the EPA registrations; the* ***concentration, application method, and contact time*** *of the disinfectant; the nature of the* ***surface material being disinfected and its compatibility*** *with the disinfectant; the amount of* ***organic compound on the surface that may inactivate a disinfectant****; the possible need to* ***maintain a residual bactericidal activity*** *of the disinfectant on the surface; the* ***corrosiveness*** *of the disinfectant to equipment with repeated application; the* ***safety*** *considerations of operators applying the disinfectant; the* ***compatibility of the disinfectant with cleaning agents and other disinfectants****; the planned disinfectant* ***rotation****; and the steps that need to be taken to* ***avoid contamination of pharmaceutical products by a disinfectant****."*

DISINFECTANT CHALLENGE TESTING

"… To demonstrate the efficacy of a disinfectant within a pharmaceutical manufacturing environment, it may be deemed necessary to conduct the following tests: (1) use-dilution tests (screening disinfectants for their efficacy at various concentrations and and contact times against a wide range of standard test organisms and environmental isolates); (2) ***surface challenge tests (using standard test microorganisms and microorganisms that are typical environmental isolates, applying disinfectants to surfaces at the selected use concentration with a specified contact time, and determining the log reduction of the challenge microorganisms);*** *and (3) a statistical comparison of the frequency of isolation and numbers of microorganisms isolated prior to and after the implementation of a new disinfectant. …"*

"… ***In practice, sufficient organisms need to be inoculated on a 2-inch x 2-inch square of the surface being decontaminated, i.e., a coupon, to demonstrate at least a 2 (for bacterial spores) to 3 (for vegetative bacteria) log reduction during a predetermined contact time*** *(e.g. 10 minutes over and above the recovery observed with a control disinfectant application)"*

"… Points to remember are that ***disinfectants are less effective against the higher numbers of microorganisms used in laboratory challenge tests than they are against the numbers that are found in clean rooms*** *…; that inocula from the log growth phase that are typically employed in laboratory tests are more resistant, with the exception of spores formed during the static phase, than those from a static or dying culture or stressed organisms in the environment: and that* ***micororganisms may be physically removed during actual disinfectant application in the manufacturing area. …"***

DIN EN Standards - Germany

DIN EN 13697: Chemical Disinfectants and Antiseptics - Quantitative Surface Test for Nonporous Surfaces for the Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants used in Food, Industrial, Domestic and Institutional Areas - Test Method without Mechanical Treatment and Requirements (Phase 2/Step 2)

FDA Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (2004)

"The suitability, efficacy and limitations of disinfecting agents and procedures should be assessed. The effectiveness of these disinfectants and procedures should be measured by their ability to ensure that potential contaminations are adequately removed from surfaces.

To prevent introduction of contamination, ***disinfectants should be sterile****, appropriately handled in suitable (e.g. sterile) containers and used for no longer than the predefined period specified by written procedure. Routinely used disinfectants should be effective against the normal microbial vegetative flora recovered from the facility. Many common disinfectants are ineffective against spores. For example, 70 percent isopropyl alcohol is ineffective against Bacillus spp. spores. Therefore, a* ***sound disinfectant program also includes a sporicidal agent, used according to written schedule and when environmental data suggest the presence of spore forming organisms****."*

Application of Regulatory Requirements for Disinfectant Qualification

Disinfectant qualification	Application of regulation/standard
Test setup	According to DIN EN 13697 can be used as reference
Test organisms	ATCC strains: USP <71> / Ph. Eur. 2.6.1 / Ph. J. 4.06 Facility-specific microorganisms: USP <1072>
Test surfaces	Company-specific surfaces according to USP <1072>
Requirements for microbial effectiveness	USP <1072>
Requalification interval	There are no specific interval for retest mentioned in regulatory requirements.

Procedure for Disinfectant Qualification

Initial qualification: Disinfectants which are to be introduced for routine application, i.e. for regular use or as backup disinfectant, are initially qualified. The initial qualification is subdivided into three steps.

Installation Qualification (IQ): Selection criteria: theoretical suitability of the disinfectant, of the manufacturer or supplier; handling and application safety (manufacturer's or supplier's documentation)	***Operational Qualification (OQ):*** Proves the effectiveness of the disinfectant under realistic conditions.	***Performance Qualification (PQ):*** Proves the effectiveness during routine application (data from environmental monitoring). The disinfectant efficacy testing is carried out as part of the OQ.

Example: *Installation qualification (IQ)*

Product (Manufacturer)	Septihol ST (STERIS), new 70%IPA	Decon-Ahol WFI (Veltek),new 70%IPA	SporKlenz (STERIS), in use sporicidal	Decon-Spore 200 Plus (Veltek), new sporicidal	VestaSyde ST (STERIS), new Quat	Process NoD ST (STERIS), new quat	DQ200C-03-2Z(Veltec associates), new quat
Active Ingredients	70% IsoPropyl Alcohol (30% PW)	Sterile 70% IPA	1% Hydrogen Peroxide, 0.08% Peracetic Acid, <10% Acetic Acid	Hydrogen Peroxide 27.5% acetic Acid 5 to 10 % paracetic acid 5.8%	Didecyldimethylammonium chloride 7-13%, Ethanolamine 5-10%, n-Propanol 1-5%, 1-octanamine,N,N-dimethyl-,N-oxide 1-5%, Alanin,N,N-bis(carboxymethyl)- trisodium salt 1-5%, ethanol 0.5 - 1.5 %	Quaternary Ammonium compounds, di-C8-10-alkyldimethyl,chlorides 5-10%, Quaternary Ammonium compounds, benzyl-C12-16-alkyldimethyl,chlorides 5-10%, Ethanolamine 5-10%, Ethyl alcohol 1-5%, Nonylphenol ethoxylates 0.1-1%	didecyl dimethyl ammonium chloride, dimethyl benzyl ammonium chloride
Efficiency	N/A		Fungicidal		Fungicidal	Fungicidal	Fungicidal
	N/A	Germicidal	Germicidal		Germicidal	Germicidal	Germicidal
	N/A	Sanitizer	Virucidal	Germicidal (lower concentration)	Virucidal	Virucidal	Virucidal
	N/A		Tuberculocidal	Virucidal (lower concentration)	Tuberculocidal	Tuberculocidal	Mildewcidal
	N/A		Sporicidal		N/A	N/A	
Usage	RTU, Trigger spray	RTU, trigger spray	RTU, Spray and wipe, mop, fogging	RTU, spray, wipe, mop, 1 gal sterile concentrate, 13oz sterile conc,	2oz in 1gal(1:64dil), wipe	1/2 oz in 1gal, wipe	2oz in 4 gal(1:256 dil)wipe
Studies (test, regulations)	Endotoxin testing via LAL, SAL of $1x10^{-6}$, sterility test of 73 days	Tested according to AOAC, EPA Registered	Tested according to AOAC; EPA Registered	Tested according to AOAC, EPA Registered	Tested according to AOAC, EPA Registered	Tested according to AOAC, EPA Registered	Tested according to AOAC, EPA Registered
Validation Report	Lot Specific Certificate of Analysis, Irradiation, Sterility and Bacterial Endotoxins Testing	Lot specific certificate of analysis, analytical validation, expiration assay, compatibility studies, Irradiation, Sterility, Container Closure, Filter Validation, Bag Integrity, in-use expiration	Lot specifc certificate of analysis, compatibility and corrosion studies, ADE and PDE Limits, 28 day opened container stability.	Lot specific certificate of analysis, compatibility studies, analyical validation, expiration assay and sterility, conatiner sterility,Container Closure, Filter Validation, Bag Integrity, in-use expiration	Lot specifc certificate of analysis, Compatibility Studies, Irradiation, Sterility, Toxicity Studies, 5 week used dilution stability.	Lot specifc certificate of analysis, Compatibility Studies, Irradiation, Sterility, Toxicity Studies, 7 day used dilution stability.	Lot specifc certificate of analysis, Compatibility Studies, irradiation, Sterility, Toxicity Studies, 30 days inuse stability
Corrosion/Compatibility Studies	Tested and safe to use on Aluminum, 304 and 316 Stainless, Vinyl curtain, silicone rubber, Kydex, PlexiGlass, Lexan, Viton, EPDM-70, Terrazzo, and Epoxy flooring.	use on hard non porus inanimate surface, tabels, counter, LFB, floors, walls, carts, shelves,glass, vinyl,chrome, SS.	Corrosion study completed and available. Safe for use on acrylic, laytex gloves, barrier insolation sleeve material, stainless steel, polycarbonate, and PVC. Incoampatible with heavy metals including iron, copper, copper alloys, brass and aluminium, saltas, flammable organis, alkalis, caustics, chlorine and formaldehyde.	304 SS, 316 SS, anodized aliminum, epoxy, plastic, vinyl, terrazzo, kidex	Compatibility Study completed and available. Safe for use on stainless steel and a variety of floors, walls and ceilings.	Compatibility Study completed and available. Safe for use on stainless steel and a variety of floors, walls and ceilings.	compatibility study available for stainless steel, tempered aluminium, PVC,Vinyl, galvanized steel, Plexiglass, ceramic tile, brass, Coated Mild steel, Rubber
Experience Report	N/A	N/A	Low residue	N/A	N/A	N/A	N/A
Additional cleaning step with WFI or IPA	N/A	no	rinsing with WFI recommended	N/A unless deemed necessary on critical surfaces.	May be needed once after maintanence or daily	May be needed once after maintanence or daily	no residue claim
Package	Individually double bagged and then gamma irradiated	Individually double bagged in an ISO Class 5 (Class 100) and then gamma irradiated. Includes VAI's ABCD Cleanroom Introduction System (quadruple bagging).	1 gal RTUIndividually double bagged and then gamma irradiated	Aseptically filled and processed into sterile components. in ISO 5 (Class 100); individuallydouble bagged.	Individually double bagged in an ISO Class 5 (Class 100) and then gamma irradiated.	Individually double bagged in an ISO Class 5 (Class 100) and then gamma irradiated.	Individually double bagged in an ISO Class 5 (Class 100) and then gamma irradiated. Includes VAI's ABCD Cleanroom Introduction System (quadruple bagging).
Packaging Unit	16oz. Trigger spray bottles or 32 oz. 1 gal bottle	11 oz aerosol; 24/case 16 oz trigger; 12/case 16 oz squeeze bottle; 12/case 32 oz trigger; 12/case 1 gallon; 4/case	1 gallon, 1qt	13 oz unit dose. 12/case (SimpleMix also available)	2oz. pouches per 144 in case; Ready-to-Use option in 1 gallon with 4 in case (other size options available)	1oz. pouches per 144 in case	2 oz unit dose. 24/case.(SimpleMix also available)
Warehouse storage	Bulky	Individual RTU bottles	Bulky	unit dose small space	unit dose small space coverage	unit dose small space coverage	unit dose small space
Preperation of Use-Solution	Ready to Use	RTU	Ready to Use	13 oz unit dose will make 2 gallons of solution	Two Options: Ready to Use or 2 oz pouches single serve size premeasured 2 gallon of working solution	1 oz pouches single serve size premeasured 2 gallon of working solution	0.5 ounce in 1 gallon WFI or 2 OZ in 4 gal WFI.
Sterility	Solution is filtered to 0.22micron, then sterilized via gamma irradiation, producing a WFI quality product (meets WFI limits in endotoxin)	70% IPA with 30% WFI filled in ISO5 filtered at 0.2 micron and terminally sterilised to 10 o 6 SAL	0.2 micron filtered and each lot is USP sterility tested,Option for EO sterilized product	Aseptically Filled, 0.2 micron filtered into sterile components in ISO5 .	Gamma Irradiated	Gamma Irradiated	0.2micron filtered, filled in ISO5, gamma irradiated, sterility tested,validated for sterility shelf life
Incoming control	CofA	C of A	CofA	C of A	CofA	CofA	CofA
Flash Point	21° C	18.3C	N/A on SDS	181.4 F	44C	not considered flammable	155.3 F
Storage	Should be stored in an area not exposed to extreme temperatures. Do not store in sunlight or temps over 48° C.	store at RT below 120F or 48.8C	store below 24C	store locked up, in original container in cool ventilated place away from incompatible materials. Keep container tightly colosed away from direct sunlight, store at temp <30C or 86F	Store in secure area away from flamamable materials. If frozen, thaw and remix before use	Store in secure area away from flamamable materials. If frozen, thaw and remix before use	do not contaminate , water, food or feed during storage
Backing Material	USP Purified Water		USP Purified Water	sporklenz, sporgon	Decon -Quat 200C		VestaSyde ST
Price							
Communication							
Personal Protection	goggles, rubber gloves, well ventilated areas	nitril gloves, goggles, well ventilated areas	nitril gloves, rubber apron, rubber boots, goggles, well ventilated areas, if air contamination is above the permitted levels, use an NOISH approved respirator.	wear chemically resistant proticctive gloves, rubber, latex, neoprene, eye protection- tightly fitting safety goggles, fae shield. Respirtory protection- observe occupational exposure limits and minimise risk of exposure. If occupational exposure limit is exceeded, wear suitable respirtory equipment. Prevent entry in to sewers and steams.the best study available demonstrated that dogs exposed to H2o2 at conc of 7ppm for 6hrs a day for 6 months produced significant irritation to lungs and bleaching of hairs.	nitril gloves, goggles, well ventilated areas	nitril gloves, goggles, well ventilated areas	rubber gloves, goggles, refer to section 8.3 of SDS
Notes	Each case shipped with a lot-specific document, which details QC, irradiation, and testing.	Each case shipped with a lot-specific document, which details QC, irradiation, and testing. productavailable and audit done	Each case shipped with a lot-specific document, which details QC, and testing.	available and audit done	Each case shipped with a lot-specific document, which details QC, irradiation, and testing.	Each case shipped with a lot-specific document, which details QC, irradiation, and testing.	available and audit done
Application mode	spray and wipe disinfection	spray and wipe disinfection	Acheives high level of disinfection at 10 minutes and complete sterilization at 5.5 hours.	spray and wipe disinfection	Just wipe disinfection	Just wipe disinfection	Just wipe disinfection
Compounding of disinfectant/Release	In coming control and release based on Cofa	In coming control and release based on Cofa	Can be diluted 1:49 and used as disinfectant.	dilution needed	dilution needed	dilution needed	dilution needed
Contact Time	30 seconds	30 secs to be copied	1 hour	10 mins for bactericidal, 6 hrs at 20C for sporicidal, as per label claim. Rep. informed 5-10 mins is enough as 6hr label claim is with 1million spore on medical devices.	Contact time 10 or 15 mins for effective fungicidal	Recommended specially for Pharmaceutical in sterile manufacturing. Contact time 10 or 15 mins	10 mins
Formulated mixture shelf life	2 years if unopened	3 years for aerosol; See VL-1500 validation previously provided for testing	1 year unopened, 28 day opned	1 yr unopened, 30 days mixed. See VL-1500 validation previously provided for testing.	35 days in deionised water and stored in closed container	7 days in deionised water and stored in closed container.	use fresh solution daily, 30 days study available
Residue validation	N/A	3,5,10 mins immersion once	60min immersion	3,5,10 mins immersion once daily for 30 days	1:16 dilution, corrosion rate (mpy) and wt change for plastics after 7 days immersion test	1:128 dilution , corrosion rate (mpy) and wt changes for plastics after 7 day immersion test	24 hrs immersion followed b wfi rinse, test repeated 6 times
316 Stainless steel		No residues	0.14g	No residues	0.02, no changes observed	<K34-0.02 , no changes observed	no change
304 stainless steel		No residues	na	No residues	0.02, no changes observed	-0.01 , no changes observed	no change
Anodized aluminium		No residues	0.21g	No residues	0.11 aluminium turned dark grey, thin layer of white precipitation noted prior to acid wash. 4.66, dark grey coupon after acid wash	0.29 coupon turned gray prior to acid wash, 0.53 very slightly darker and smoother	no change
epoxy		No residues	na	No residues	Epoxy flooring2.46, no observed changes	epoxy flooring, 2.64 no observed changes	n/a
plastic		No residues	na	No residues, slight after 30days	n/a	n/a	N/A
vinyl		No residues	na	No residues, slight after 30days	-0.32 stiffer coupon, solution turned cloudy	-0.05, very slightly stiffer coupon	no change
terrazo		No residues	na	No residues	n/a	n/a	N/A

Operational Qualification (OQ):

Test setup is based on USP 1072 and DIN EN 13697 as applicable.

Test surfaces for disinfectant study is based on material installed or used in Cleanrooms

1. Stainless Steel - with and without organic contamination as per DIN 13697
2. Glass
3. Plexiglass
4. Terrazo (Flooring)
5. LF curtain
6. Aluminum
7. Fiberglass Reinforced plastic (Walls)
8. Nitrile
9. Tyvek
10. Polyethylene (e.g. outer packaging of media, RTU PPM etc)

Other materials present in Cleanrooms but does not have significant amount of surface area, perform comparability and justify in risk assessment and do not forget the CCS as well !

List of Surfaces Installed and Evaluation of Relevance for Disinfectant Qualifications

Sufrace material VDSC	Use of surface	Relevance for disinfectant qualification	Explanation of relevance
Cleanroom surfaces (incl. filling equipment) - Grade A/B			
Terrazo	Floor	Yes	Surface material is inside zone A/B and is only treated with disinfectant.
PVC-soft, crystal-clear	LF curtain	Yes	Surface material is inside zone A/B and is only treated with disinfectant.
Stainless steel 316	Cover sheets of filling equipment / barrier struts / any permanently installed equipment (e.g. rail systems, magazine carts) / switch cabinets / furniture / wall covering/ Mop handles & Holder.	Yes	Surface material is inside zone A/B. Permanently installed equipment is only treated with disinfectant.
Stainless steel 304	Mobile Cleanroom Stool top surface as an aid to operator for resting.	No[3]	Surface material in Grade A/B treated only with disinfectant. No direct/indirect product contact to signify its inclusion in study
Makrolon® (Polycarbonate) or Lexan or plexiglass	Covers / barrier / cover of ceiling lighting, Camera lens in Cleanrooms	Yes	Surface material is inside zone A/B. Permanently installed equipment is only treated with disinfectant.
Aluminum	Sterilization boxes / equipment components / aluminum profile (e.g. return air channel) Carts	Yes	Surface material is inside zone A/B and / or Permanently installed equipment is only treated with disinfectant.
Teflon, POM white/black (polyoxymethylene)	Syringe conveyor rails / telephone holder / various small parts/ Hose for gas	Yes[1, 2]	Surface material is only treated with disinfectant.
Glass windows	Cleanroom windows / touch screen/ Mirror	Yes	Surface material is inside zone A/B and / or Permanently installed equipment is only treated with disinfectant.
Silicon	Hoses / joints / tool handles / transportation straps/ Sensor shields	Yes[1]	Surface material is only treated with disinfectant/ some introduced via autoclaving
PEEK (Polyetheretherketone)	Various small parts / equipment components / syringe clips, Format parts	Yes[1,2]	Surface material is only treated with disinfectant.
Fiberglass renforced plastic	Cleanroom walls	Yes	Surface material is only treated with disinfectant.
Plastic, general (not known in detail),Teflon, Delrin, Nylon casters	Operating panel of equipment / sensors / handles/ LF grids/conveyor belt/Cleanroom stool	Yes[1]	Surface material is only treated with disinfectant.
Plastic/rubber (not known in detail)	Mop handle holder	Yes[1]	Surface material is treated with disinfectant.
Teflon white	RABS Glove port covers	No	Material introduced after autoclaving, stored and cleaned with Cleanroom if not used on RABS.
Surface material	Use of surface	Relevance for disinfectant qualification	Explanation of relevance
Cleanroom surfaces (incl. equipment) - Grade C			
Same as A/B	Same as grade A/B	See grade A/B	See grade A/B
Glass	Product/media containers	No	materials used after autoclaving
Plastic	Single use plastic bags/ cleaning buckets	No	materials used after autoclaving
Nitrile / Tyvek	Gloves / Gowning material	Yes	material is treated with disinfectant.
Granite: Floor like material	Table top in Compounding area for holding Scale for stability	Yes	Surface material is treated with disinfectant.
Stainless steel	Furniture/ Flexboy carts / weighing carts/ table top in LF of compounding room	Yes	Surface material is treated with disinfectant.
Aluminium	Aluminuim frames in Grade C areas for displaying control signs	Yes	Surface material is treated with disinfectant.
Surface material of mobile equipment (e.g. tubs, etc.)			
Stainless steel	Sterilization cart / cabinets etc.	Yes	Surface material is treated with disinfectant and introduced into grade A/B.
Plastic (not known in detail)	Hose pumps / sensors / castors for mobile equipment/ eye wash station in Grade C	Yes[1]	Surface material is only treated with disinfectant.

Test Microorganisms

Reference microorganisms used to test the bactericidal properties:

Escherichia coli	ATCC 8739
Pseudomonas aeruginosa	ATCC 9027
Bacillus spizizenii	ATCC 6633

Reference microorganism used to test the sporicidal properties:

Bacillus spizizenii	ATCC 6633

Reference microorganisms used to test the fungicidal or yeasticidal properties:

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

Facility-specific microorganism of the group of microorganisms:

Micrococci/staphylococci
Gram-positive rods (not used for suspension tests)
Gram-negative rods (facility-specific microorganisms)

for testing of bactericidal properties.

Facility-specific microorganism of the group of microorganisms:

Sporulating aerobes

for testing of sporicidal properties.

Facility-specific microorganism of the group of microorganisms:

Molds
Yeasts

for testing of fungicidal or yeasticidal properties.

Test Setup

Consider following parameters for disinfectant qualifications:

- Concentration of disinfectant
- Contact time with disinfectant
- Holding time of prepared disinfectant solutions
- Challenge needed surfaces with and without organic contamination simulation
- Mimic your real-life cleaning process or your proposed clean up plan to implement after disinfectant qualification e.g., application of disinfectant by spray and moping during the qualification process

Acceptance Criteria for log reduction of the disinfectant tested within the scope of realistic surface testing:

Tested with vegetative microorganisms (bacteria):	at least 3 log reduction
Tested with spores (bacterial spores, mold spores and yeasts):	at least 2 log reduction

Results

- In theory disinfectant study should meet the acceptance criteria and thereby comply with regulatory requirements.
- However not all the surfaces, M.O, disinfectants and contact time combinations meet the log reduction criteria.
- Investigate the test performance for Disinfectant efficacy, dilutions, calculations, suitability of the recovery method, neutralization of disinfectants etc.
- In that instance repeat the test with another suitable disinfectant if possible.
- Consider increasing contact time.
- There should be at least one disinfectant which is effective against the non-conforming test M.O for practical applications!

Risk Assessment to Acknowledge Disinfectant Efficacy Test Results

Once the report is finalized for Disinfectant efficacy testing RA is created justifying acceptance of results obtained from the study.

Test your newly qualified Disinfectant regimen by cleaning followed by EM for your Manufacturing areas (Grade A/B/C/D) for 3 times and evaluate microbial recovery as part of OQ.

Some points for a RA:

- Background of the RA
- Aim of the RA
- Facts and Data- DE study data, Media fills, EM trends, Microbial recovery across critical areas Vs DE log reduction obtained
- Assessment – Demonstration of contamination control via Engineering controls, Material and personnel flow, Cleaning agents, rotation of bactericidal vs sporicidal, process controls, Viable and Nonviable trending etc.
- Revise the Risk assessment after 2 -3 yrs of experience with use of disinfectants in use with more data backing up control of microbial recovery in manufacturing areas

Performance Qualification (PQ):

- The disinfectant is tested for concentration and exposure time is qualified for your routine use during OQ.
- Provides evidence of effectiveness during routine application using your currently specified facility-specific microorganisms.
- Reference ATCC cultures as per <1072> do not need to be tested during PQ
- Species that have been defined as facility-specific microorganism in the past, need not to be tested during requalification, as the disinfectant was tested and demonstrated successfully in the past. Such recurring facility-specific microorganisms are a different strain of the same species.
- Disinfectants which are only effective against vegetative microorganisms are not tested against sporulating microorganisms.
- Disinfectants which kill vegetative microorganisms and spores are only tested against sporulating microorganisms but not against vegetative microorganisms.
- Sporicidal disinfectants are only tested against spores but not against the vegetative cells of the sporulating microorganism.

Non-Routine Qualification

In addition to initial qualification (OQ) and the regular requalification (PQ), situations may require the qualification or suitability testing of a qualified disinfectant already in use. For example, this may occur during special investigations or due to non-conformities in environmental monitoring.

In these non-routine cases, the test conditions and specifications for a successful test are as specified for the initial qualification or requalification. The surfaces to be tested, the testing with or without organic contamination and the test organisms are variables that may be designed to focus on the specific problem.

When all set and done with Disinfectant qualification testing – do not forget to update your contamination control strategy !

Thank You !