

VALITEQ[®] DMS v2.0

Document Management Software Tutorial

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TEXT APPEARING IN BLUE CONSITUTES GUIDANCE, ONLY

PRODUCT OVERVIEW

The DMS 2.0 is a powerful Quality Management tool designed to assure the Continuous Quality Improvement (CQI) of your Compounded Sterile Preparations (CSP's). The DMS 2.0 is a Java-based program designed to operate on any hardware system, from a laptop to a server accessible by many users. It provides a timely and integrated approach to your personnel, facility, and environmental management issues.

As you add future DMS modules to your system, you'll gain greater control of your CSP program through complete Preparation Audit and testing Processing Equipment Documentation, Process Auditing and Statistical Process Controls, or 'SPC's.

The DMS v2.0 automatically schedules routine training, testing, and environmental monitoring of personnel, rooms and engineering control equipment. Data is automatically compared to industry standard limits, and is color-coded to provide compliance at a glance. The program is easy to setup, and includes a video tutorial illustrating the major features and setup methods to assist you with setup and operation.

Alert, Action, and Fail Limits

Operational Alert, Action, and Fail Limits are established for individual process control parameters, such as airflow, particle counts, air pressurization, microbiological contamination, and operator performance which are necessary to maintain the integrity of the CSP process.

Alert Limit. An Alert Limit is a testing value or level of performance that signals the possibility of a deteriorating trend. No corrective action is required at this level, however, increased vigilance and/or testing to confirm the trend should be carried out and documented. Although USP <797> does not require Alert Limits, these limits are necessary to establish and analyze trends before a deteriorating situation gets out of control.

Action Limit. An Action Limit is a testing value or level of performance that signals the need for immediate corrective action to reverse a trend before the Fail Limit is reached. USP <797> requires that action limits be determined.

Fail Limit. A Fail Limit is a testing value or level of performance that signals the deterioration of a process parameter to a point beyond which there is no assurance that the sterile preparations being compounded will be of acceptable quality. If a Fail limit is met or exceeded for *any critical process control parameter*, operations **must be halted** until the out-of-limits condition or situation is corrected.

Because halting the CSP process this is not always feasible in a compounding pharmacy, Alert and Action limits are established to alert the operator to a deteriorating trend, and allow corrective action prior to the need to halt the process. In this manner, exceeding the Fail Limit can be avoided in most cases.

Color-Coding: The DMS v2.0 incorporates color-coding to make it easy to spot trends. **Red** entries at, or above the Fail Limit occur either automatically (i.e., microbial monitoring Fail Limits are established in reference to the USP guidance chapter <1116>), or may be established by the Administrator during set-up. Action Limits appear in **orange**, and Alert Limits appear in **lime-green**. **Dark green** is used to indicate values that are within the acceptable operating range.

SETTING UP THE DMS v2.0

Change Passwords

Passwords can be changed by the Administrator and any users who have been assigned the authority to change their own password from the 'OPTIONS' Menu. Select 'Change Password'.

Enter the old password, and then the new password twice.

Forgotten Passwords

If any user OTHER THAN the Super Administrator forgets their password, an administrator can set a new password in the 'Manage Security Users' section of the 'OPTIONS' menu by selecting the Security User and Selecting 'Edit User'. It is not necessary from this option to know the old password. Simply enter the new password twice.

It is a very good idea for the Super Administrator to set up a new Administrator User for their own daily use and to assign administrator status to at least one other highly trusted individual.

Manage Personnel

Add Personnel

Personnel can be added by selecting 'Manage Associates' from the options menu. This will bring up the Associate details entry screen, which is self-explanatory. After saving an Associate, you can click clear to add another. Associates may be deleted from this menu; however, they can be archived from the Individual Training Data record, which allows you to retain their records, while removing them from the training and testing schedule.

NOTE: Adding personnel in this screen does not automatically generate an Individual Training Data Record (ITDR), and personnel can be added directly from the 'Create ITDR'

function. At least one supervisor should be set up in the 'Manage Associates' section, however, because you are required to indicate a supervisor on each ITDR.

Add Users

Any and all Associates can be provided with access to the program through the 'Manage Security Users' selection of the Options menu. See 'Access Levels and Security Users' for details of the functions each access level provides.

Access Levels and Security

The VALITEQ® DMS v2.0 comes with a default Super Administrator, who cannot be deleted from the program.

There are three levels of access that can be assigned to additional users; Administrator, Supervisor, and Tech Users.

Administrators have access to all aspects of the software, however, unlike the Super Administrator, they can be deleted. It is a good idea for the Super Administrator to create an Administrator identity for daily use. Only Administrators can manage Associate set up and passwords, create training data records, print test keys, and set up facilities and equipment. This prevents others from altering the approved testing and process performance requirements. Only Administrators can cancel erroneous data entries to permit correction of errors.

Supervisors can enter personnel, room, and equipment testing results, and print written tests. Supervisors may also add or edit SOP's for training and record keeping purposes.

Tech users may only add data to existing room and equipment records.

Create Individual Training Data Records (ITDRs)

From the 'Training/Testing Records' menu, select 'Create ITDR'. Select the Associate from the pull down list of personnel added in 'Manage Associates' or click on the icon to the right of the pull down menu to add an Associate. Select a supervisor from the pull down list, and set the training and testing frequency. This is usually annually for low- and medium-risk operatives.

Set the initiation date when you want record keeping on the individual to begin. This will create a testing schedule for microbial sampling of the personnel's gloves, gown, and active airborne sampling near their compounding zone based upon the frequencies of testing you select. The frequency of microbial testing selected will be based, in part, upon the amount of time the individual is scheduled in compounding, as well as on-going

sampling results. For those personnel who work full-time in sampling, we suggest that gloves and gowns be sampled at least once per week, initially.

Active microbial sampling conducted adjacent to the work zone of operative personnel as compared to static sampling conducted under at-rest conditions may provide an indication of the amount of disruption the operative creates, and the level of debris and contaminants they generate during compounding. We recommend that personnel work zones be sampled at least as frequently as their normal re-verification is scheduled.

Select 'Training' and 'Testing' frequencies. For low- and medium-risk personnel, this is usually 'annually'. Also select an 'Observation' frequency. Again, this will depend on the amount of time the individual spends in the CSP process. For individuals who work full time compounding, we recommend that you select 'weekly' in order to achieve the recommended level of observation.

Conducting Graded Observation

It is important that observation be conducted based upon an objective set of criteria, and that it is scored in a consistent manner in order to track progress over time. We recommend that you use the 'Assessment of Aseptic Technique' form included under the 'Forms' menu.

The 'Assessment of Aseptic Technique' form should be used for documenting and scoring all practical verification sessions. Personnel should be allowed to examine the form prior to testing, to assure they understand what is expected of them, and how they will be scored. The form should then be used on an ongoing basis to document observations. When performing observations, not all items on the form may be included in the compounding being conducted. For those items that are not observed on a given occasion (for example, use of an ampule or an automated compounder), mark NA in the 'Points Achieved' column. Determine the percentage of compliance based upon the number of 'Possible Points' with the NA items omitted. The minimum acceptable score for all practical test exercises and observations is 90%.

Training and testing, both written and practical, in Aseptic Technique are automatically scheduled based upon the initiation date you enter for the individual. After testing has been completed and the data entered, recurrent testing is scheduled based upon the last date of testing and the frequency you select. For personnel who compound hazardous drugs, testing in Aseptic and Containment technique, both written and practical, is not scheduled until you initiate it by entering the first data for these categories.

Adding Data

Once an ITDR has been saved you may enter records of materials issued, training provided, and testing conducted by clicking on the appropriate label in the 'Report Data' section. When adding data for scheduled events you must:

1. Select the schedule item for which you are adding data. This is extremely important. If you forget to do this, the program will prompt you to select a date when you attempt to save the data, and you'll have to begin again.
2. Enter the desired data. Comment sections are provided in many instances, but are not required. All other data is required.
3. Click 'Save'.
4. To add additional data of the same type, click 'Clear', then proceed as above.

Initiation Dates and Schedules

The initiation date is the date upon which record keeping in this DMS v2.0 begins. The program will begin scheduling tasks as of that date. If data is not entered, the entry will show a red No Data. Its value will be calculated in all averages as the fail limit plus one unit of measure.

Schedules are set based upon the initiation date and the frequency you set. All weekly items are due within the week beginning on the due date listed, monthly items are due within the month following the due date listed, and so on. For pressurization frequencies, you have the choice of Daily, or Each Shift. The schedule dates for the room and all equipment associated with it will be based upon the selection you make and the days and shifts of operation you indicate in room set up.

Vacations, Leaves of Absence, and Illness

If personnel will be temporarily absent over a time period that would normally include testing, observation, or other scheduled activities, scheduling can be suspended by placing the 'Individual Training Data Record' (ITDR) in the 'Archive'. This is done by simply clicking the 'Archive' button on the bottom of the individual's record. Archiving suspends all scheduling. Normal scheduling will recommence when the archived file is reactivated. This process also can be performed for items of equipment or rooms that are temporarily out of service.

Importing Records

When you import personnel records from the DMS v1.1, you must change their initiation date in this program to the date at which you wish to begin recording

data about the personnel. All old data will be retained. However, the program will ask for new data regarding microbial sampling based upon the frequency you selected and the initiation date.

Retesting

Both administrators and supervisors can schedule additional retesting for data that is out of limit or within the alert or action limit levels by clicking 'Retest'. This inserts a new data line in the chart on the right of the screen. Select this line to enter new test data.

Correcting Erroneous Data Entries

If a mistake is made, an administrator can cancel the data. This inserts a new data entry line for addition of the correct data. To add the corrected data, click on the newly inserted line and proceed as usual. This function is reserved for administrators so they can verify the correct data. A permanent record of the incorrect data entry is maintained.

Add SOPs

If you wish to document that personnel have received SOPs and other training materials, this may be added by either an administrator or a supervisor in the 'Utilities' Menu. They will then be available in the Manuals/SOPs section of the ITDR for documentation. Click 'clear' after saving to add additional items.

Create Room Data Records (RDRs)

Rooms are set up from the 'Create RDR' menu. Several different Room functions are offered, as well as several ISO Cleanliness Class designations. The 'Critical Aseptic Work Zone' function should be used for custom stations, and should always be certified to ISO Class 5, or better. Certification of rooms and equipment used for low- and medium-risk compounding must be conducted at least every six months.

'Buffer Zone' should be used for any rooms in which LFCBs or BSCs are located, and should be certified to ISO Class 7, or better.

'Anteroom' should be selected for cleanrooms which directly access the Buffer Zone. These may be ISO Class 8, or better.

'Support Areas' are unclassified areas, such as store rooms, where you may wish to document cleaning and conduct microbial sampling. Compounding Aseptic Isolators (CAIs) might also be located in a designated Support Area.

The days and shifts of operation set for the room are used to schedule testing and sampling activities for the room and *all equipment* associated with it. This is an important function, particularly for those activities that are scheduled each day or shift, such as cleaning and disinfection, or pressurization checks.

When you set up microbial sampling you will need to select the frequency *and* the number of locations to be sampled. (If you leave the number of locations at the default 0, no sampling will be scheduled).

Microbial Monitoring

Monitoring of the bioburden on critical surfaces and in the air of controlled facilities can provide information about the efficacy of cleaning protocols and the adherence of personnel to good aseptic practices. Microbial monitoring must, however, be conducted with care to derive useful information. Microbial plates should be handled carefully and examined and counted frequently. This will assure that individual colonies can be distinguished before they merge, or overgrow and obscure other colonies, thus making enumeration impossible.

Airborne sampling is best conducted with a sampler that actively samples a known quantity of air and that is designed to ensure capture of the organisms on the growth medium. It should be noted that centrifugal samplers that draw very large samples may not be suitable for use in Laminar Flow equipment, because their sample rate may exceed the supply rate of the unit, resulting in air being unevenly drawn, returned to, or drawn from outside the critical work zone (i.e., anisokinetic sampling).

The terminology of airborne sampling is somewhat confusing. The term 'active' means one thing when considering sampling methods, but something else when considering sampling conditions. The *method* of sampling may be passive (i.e., settle plates), or active (a known quantity of air is drawn through the sampler with a pump). The *conditions* of sampling can be static (at-rest, no activities being conducted) or active (adjacent to, or during normal activities).

USP <797> proposed revisions require that active air sampling be conducted at least monthly in areas where low- and medium-risk CSPs are prepared. The results are reported in Colony Forming Units (CFU) per cubic meter of air sampled. Older USP chapters, such as <1116> reported CFU per cubic foot of air sample. One cubic meter equals 35.31 cubic feet. Initially, and periodically thereafter, a 1000 liter (one cubic meter) sample should be used to establish: 1) the approximate microbial cleanliness in an area, b) likely problem locations, and c) a historical basis for revision of the sampling plan. Based upon the results, it is likely that a 300 liter sample may be adequate for areas that are likely to be very clean. In areas that are likely to be dirtier, a sample of 200, or even 100 liters may be desirable in order that the plates do not overgrow too rapidly to be properly

quantified, or that plate crowding not skew enumeration. Experience will help you determine a sample size that catches enough organisms to be representative without capturing so many that quantification becomes problematic.

Surface sampling may be conducted using swabs or contact plates (such as the EnviroAssay™ Surface Monitoring System). We recommend the plates for their ease of use. It is difficult to sample consistently over time with swabs, because the area sampled will vary and the force applied may vary and affect the outcomes. Results should be reported in CFUs per contact plate or equivalent area sampled.

It is important to conduct training-oriented surface monitoring in order to both verify the acceptability of operating conditions, and to illustrate the potentially negative impact of personnel activities. Activities such as frequent re-sanitizing of gloved hands and worksurfaces may profoundly affect the integrity of the CSP process.

When multiple sample locations are selected for an item, such as counter/worksurface, data is entered as follows:

1. Select the due date for which data is being entered.
2. Enter the actual date of testing, the result, any comments, and a comments follow up date if desired. (Note that the label 'Location 1' appears to the right of the result entry field).
3. Save.
4. Select the due date again.
5. Click 'Clear'. (Note that the label next to the result entry field will change to 'Location 2').
6. Enter all data for the second location and save.
7. Continue until all location data has been added.

Setting Pressure Limits

In the DMS v2.0, the Alert, Action, and full green Normal Operating range are determined by adding 0.01 inches of pressure Water Column (W.C.) to the absolute value of the fail limit you set. Please note that you must also select and record pressure as either positive (+) or negative (-). All values recorded with the wrong sign will appear as fails.

Rooms

Within solid wall clean spaces, pressure is a quick indicator of the performance of HVAC equipment. You cannot be sure that your cleanroom is clean just because the pressure *is* correct, but you can be sure that it is not operating properly if *it is not*. A sudden drop in pressure may indicate that a fan is not functioning, that a serious breach of room integrity has occurred, or that a damper has changed position. A more gradual decline in pressure may indicate that filters are loading, or that fan components need service.

Consult with your facility designer to determine the minimum pressure value below which you should not operate in the room. The value you select will appear as a red fail. USP <797> proposed revision states that ISO Class 7 cleanrooms should have at least a +0.02" W.C. pressure differential relative to adjacent areas. In this case, setting the fail limit at +0.01" would result in the orange action limit occurring at +0.02", with alert and full green limits of +0.03" and +0.04" respectively. In the case of a Hazardous Drugs Compounding facility, the buffer area should be negative to the anteroom, with the anteroom positive to both the buffer area and the outside environment.

Setting Air Change Limits

Air cleanliness is a function of three factors: a) filtration efficiency, b) particulate generating activity, and c) air change rate. Assuming that filters are functioning properly and activity levels are stable, the air change rate determines how quickly particles are taken from the room, and therefore, its *operational* cleanliness. Declines in air change rates may indicate filter loading and/or deterioration of the air handling units. They should be determined each time your facility is certified.

Consult your room designer to determine the minimum number of air changes required for your facility and process to maintain the required cleanliness level. This will be the fail limit you set in your program. If you cannot obtain satisfactory particle count results at the level selected, you may need to decrease particulate generating activities, increase filtration and airflow, or both.

In some cases, the filtration provided by Horizontal or Vertical Flow Cleanbenches may contribute to the filtration air changes for the room. Ask your certifier to calculate the air change value of the filtration provided by your cleanbenches, and add it to the room filtration value to calculate total air filtration changes. It is important to note, however, that room pressurization can only be achieved by the addition of more filtered air to the room than is taken out or allowed to exfiltrate.

In the DMS v2.0 the Action Limit is between the fail limit you set through 110% of the fail limit. The Alert Limit is between 110% and 115% of the fail limit, and the full green safe operating limit is 115% of the fail limit and above.

About Particle Count Limits

A well-designed cleanroom will normally function far below the specified cleanliness limit, usually at or below 25% of the room Classification, under operating conditions. Particle Count testing is usually not conducted under worst-case conditions (if for no other reason than that personnel tend to adhere more strictly to gowning and activity protocols when testing is being conducted). The Alert Limit extends from 70% of the Fail Limit to 85% of the Fail Limit, while the Action Limit extends from the Fail Limit 85% of the Fail Limit.

Create Equipment Data Records (EDRs)

All equipment must be associated with a room. The schedule of operation for all equipment is assumed to be the same as that selected when the Room was set up, and planned activities are based upon that schedule. It is important to select the correct equipment type because only the appropriate Equipment features will be presented for data entry. For example, for Laminar Flow Cleanbenches (LFCBs), the duct pressurization, work chamber and pass-through chamber pressurization, undertray testing and pass-through chamber testing are deactivated, because they do not apply. For Biological Safety Cabinets (BSCs) and Compounding Aseptic Isolators (CAIs) the duct pressure section is only activated if 'Yes' is selected for 'Ducted Outside'. Fields relevant to the undertray area are activated for BSCs and CAIs, while the fields relevant to the work and pass-through chambers are activated only for CAIs.

Exhaust Ducts

It is critical that exhaust ducts intended to remove hazardous vapors from Biological Safety Cabinets and negatively pressurized Compounding Aseptic Isolators be negative, and meets or exceeds the manufacturer's minimum design specification. Back pressure on the unit caused by insufficient exhaust demand may interfere with unit operation. Positive pressure in the ducts may force hazardous fumes into the facility.

Consult the manufacturer and your certifier to determine the pressure above which your unit is not safe to operate. Set this as your red fail limit. The full green operating range will be 0.03 inches lower than this. For example, if you set the fail limit at -0.14" W.C., the full green operating range will be -0.17" W.C. (Note that the absolute value of the operating pressure is the fail limit plus 0.03).

Compounding Aseptic Isolators

Compounding Aseptic Isolators (CAIs) are designed to be either positive or negative. The pressure values should be set in a manner similar to that described for exhaust ducts. Note that some isolators employ a pass-through chamber purge feature, rather than pressurized constant-flow air. In this case, select NA for the

pass-through chamber pressure. In the case of CAIs, you must select either plus, or minus for your pressure values. CAIs used for compounding hazardous drugs must be negatively pressurized and should be ducted to the outside via negatively pressurized ducts.

ARCHIVES

Any personnel, equipment, or room can be placed into the Archive section from its active ITDR, RDR, or EDR. This halts all scheduled testing. Archive of a record might occur if personnel are on vacation or leave of absence, or when a piece of equipment or room is out of service awaiting repairs. Scheduling will re-commence when personnel, rooms, or equipment are reactivated from the Archive menu.

Placing a Room in 'Archive' automatically archives all associated equipment, however, equipment may be individually reactivated. Returning a Room to 'Activate' does not automatically reactivate the equipment. (This is done because the room may require certification and clean down prior to the reactivation of the equipment.)

REPORTS

There are many ways to print reports. The two main categories are 'Planned Activities' and regular data reports.

Planned Activities can be printed for 'Personnel Training and Testing', 'Room Testing', 'Equipment Testing', or combined 'Microbial Testing' for all categories. Simply select the desired category, enter the date range of interest, and search. If you wish to print planned activities for only a specific room and the associated equipment, you can temporarily place the other rooms in Archive. The combined 'Microbial Testing' report is particularly useful for planning the ordering of sampling supplies.

Data reports can be printed for any date range of interest. Individual ITDRs, RDRs, and EDRs can be printed from the bottom of the respective page in the 'View/Update' mode. Individually-printed ITDRs can be added to personnel files for demonstration of competency

The 'Reports' menu offers two selections: 'Summary with Details', which includes individual data values, and 'Summary with Averages', which is an abbreviated report. Averages are determined for all data types. Any 'No Data' result, which occurs if activities are not conducted or reported, is calculated at the fail limit plus one unit, and counts as a fail. When printing Personnel reports, you may select a variety of data to include, or 'Select All'. You may also elect to include archived data. For room and equipment reports you need only select whether or not to include archived data.

For guidance on use of the program, please feel free to contact Lab Safety Corporation at 877.699.7304.