A Brief Introduction to Goldplate™

for Environmental Monitoring of

Aseptic Manufacturing and Pharmaceutical Clean Areas

Goldplate
Introductory Guide

You probably don't want to read an entire manual to answer the question *'is the Goldplate system for me?'*

So here on the first page is a top level overview –we'll keep it brief but of course there is an awful lot more functionality available than an overview can describe.

What it is and what it does: Goldplate is an entire clean room plate monitoring, reporting, prevention & correction and management system that integrates clean room operations with laboratory reporting assigning those tasks to appropriate operators. It provides analysis tools – graphical and report based which allow you to be certain that your clean rooms are being properly monitored and any issues rectified. ! In short, Goldplate was developed from a working unit / laboratory. If it was needed – it got built and tested. It has been working operationally for two years.

Goldplate uses task based workflows which are generated for the laboratory, the prevention correction teams and the supervisors. Each stage of the process is clearly labelled and the work of each team is available to supervisory staff.

Trending and analysis is an important part of the system which allows you to identify any problem areas from individual areas right down to individual plates. Reports showing monthly overviews of operational areas (we call locations) provide a familiar feel to those who are used to paper based systems. Goldplate contains an automated over-view monitoring tool that can optionally be set to email management with star-rating reports and organism distributions.

Other tools allow you to see the distribution of organisms by type and area between set dates. For example you may be interested to know if a spell of wet weather has caused any fungal increases in a certain area / overall. Goldpate can record to Genus - Species level.

Setting up Goldplate to cover your department is straightforward. You can chose to set up your own locations (such as aseptics) and then add plates grouped by sessions – daily / weekly etc. or you can use one of the templates – enter 'asep' and have the system generate all of the aseptic plates for every session automatically. You can edit the plate names afterwards if required to suit local practice.

When you register for a free trial period, we suggest you experiment for a while setting up and using as a test system. After becoming familiar the 'owner' who is the person who registered can perform a factory reset on the system (as many times as you like) and then work on an operating system can begin. Incidentally, the 'owner' has the privileges to invite other users via email signups to the various team member-types.

Where is our data, and is it secure? For extreme resilience and security data is stored on our commercial quality servers, but it is always belongs to you and is available to download anytime you wish.

Need extra help? Please go online to goldplatesolutions.com where you'll find training videos and other support media. You may also contact us at info@goldplatesolutions.com

The following pages are a more expanded description of Goldplate – but are still in a brief format.

Essential Understanding: **Locations and Groups** and Working Sessions

Locations:

A <u>location</u>* in Goldplate is what you might usually refer to as a 'room' here are some examples:

Location	Abbreviated to (where appropriate)
Aseptics	Asep
TPN	TPN
Radio Pharmacy	RP
Cytotoxics	Cyto
etc.	

* We use the term location rather than room as experience has taught us that there are times when plates need to be monitored in unexpected circumstances – such as when monitoring a new temporary unit – or areas such as general floor monitoring which are common to connected rooms.

Groups:

Groups are a <u>Location + a Frequency</u>

Frequencies are built into Goldplate:
Sessional - weekly - monthly - quarterly - annually and biannually

So a 'group' is named by a *Location + Frequency*.

Examples: Asep Sessional - Asep Weekly - TPN Sessional - Cyto Monthly

Plates are located under Groups – for example here is the group *asep weekly* and its plates:

Working Sessions: Goldplate supports up to three sessions per 24 hours: am, pm and overnight

A little more on Locations and Groups…

You can automatically generate an entire set of plates for a location using the tools:

Entering Cyto and 'generate plates' will create ctyo sessional, cyto weekly, cyto monthly and cyto quarterly groups and all of their plates! (as well as defining their media type and alert / fail limits) That's more than 100 plates defined in less than a second!

Or you can choose to make your own locations and groups:

Here we have made TPN4 a location, and to that we can add a frequency to define a new group – we could chose 'sessional' which makes the group TPN4 Sessional

And to that group TPN4 Sessional we can manually add plates – defining their name, media type and warning fail limits:

On the CFU entry page we find the new group:

and pressing process opens the following page – as the system Knows the group is empty:

Produces a group with one plate…

Tips: You can add as many plates as you like to a group – but we suggest limiting the numbers to keep the data entry screen from requiring the user to scroll up and down (depends on screen resolution – but about 15-20 plates per group is fine)

We strongly recommend you use a 2 or three character prefix to the plate name – such as F1 or 4A as these will make data entry for your staff easier and viewing monthly sheets is more intuitive.

Goldplate work flows:

The cfu count of a plate is entered. If that number is below the alert level – it is a 'pass' and is simply recorded [green tick]. No further actions are required.

If the cfu number is at or above the alert level but below the fail level, a 'cautionary fail' is initiated [yellow exclamation]. A laboratory task, and a prevention correction task is raised at 'alert level'.

If the cfu number is at or greater than the action level – a fail is initiated [red exclamation]. A laboratory task, and a prevention correction task is raised at 'fail level'.

*One can also manually promote a **pass** cfu count to a **cautionary fail** – for example when colonies have a fungal appearance.*
This will also raise tasks.

The possible outcomes:
    pass – alert - fail

	CFUs	by Op	review	fail	⚖
1 settle clean room table TSA	4	-	25	50	✓
2 settle isolator LH hatch TSA	3	-	2	5	❗(yellow)
3 settle isolator L Op prep area TSA	0	-	0	0	✓
4 settle isolator R Op prep area TSA	1	-	0	0	❗(red)

Alts and Fails now enter the processing stream of the laboratory and the prevention / correction teams. A Supervisor stream monitors all progress.

Laboratory:

The laboratory receives the physical plates (with a consignment list if desired) then count and identify the colonies, entering those findings using their laboratory task list and entry screen. As each item is completed, it is removed from the laboratory task list and placed into the laboratory executive task list where a senior member of staff can optionally review and comment on the results. As each item is processed it is removed from the executive task list.

Laboratory investigation of CFUs:

Group	Item	Type	Count	Limit	Plate date	Session	Logged	
Cyto sessional	6 settle isolator RH hatch TSA	fail	6	5	Fri.04-Jan-2019	am	Fri.22-Mar-2019 15:54	progress .
Cyto sessional	6E settle room hatch (enter) TSA	alert	28	50	Fri.04-Jan-2019	am	Fri.22-Mar-2019 15:54	progress .
Cyto sessional	C2 contact isolator L Op Rh glove TSA	fail	2	0	Thu.03-Jan-2019	am	Fri.22-Mar-2019 15:53	progress .

Prevention and correction:

The prevention and correction team receive the alert / fail item into their task list, and now process each item with the actions that are taken to resolve the issue. They are assisted by a summary of the results entered by the lab, and the cfu history of the plate. When they have completed their item – it is removed from their task list.

Precautionary and Remedial Actions Worklist:

Group	Item	Type	Count	Limit	Plate date	Session	Logged	LabWork	-
Cyto sessional	5 settle isolator RH hatch TSA	fail	6	5	Fri 04-Jan-2019	am	Fri 22-Mar-2019 15:54	Incomplete	progress ..
Cyto sessional	6E settle room hatch (enter) TSA	alert	20	50	Fri 04-Jan-2019	am	Fri 22-Mar-2019 15:54	Incomplete	progress ..
Cyto sessional	F1 contact isolator L Op LH glove TSA	fail	1	0	Thu 03-Jan-2019	am	Fri 22-Mar-2019 15:53	With Lab Exec	progress ..

Monitoring:

Goldplate provides a Supervision task-list where you can see the status of each task – and optionally expand it to show the work that has been completed:

HOME | ADD SYSTEM USERS | CFU ENTRY | LABORATORY | LAB EXECUTIVE | PREVENT & CORRECT | **SUPERVISE** | REPORTING | TOOLS | LOGOUT

category: CFU limit exceeded

Overcount date	Session	Group	Item	CFUs	Alert level	Fail limit
Wed 09 Jan 2019	am	Cyto sessional	5 settle isolator RH hatch TSA	7	2	5

current laboratory results:

Lab date	Lab CFUs	Gerus	Species	Comments
15 Apr 2019 00:00	7	CNS	CNS Sp.	G-Ve environmental

recent CFU entries (initial counts)

Over limit — Cautionary level — In limit
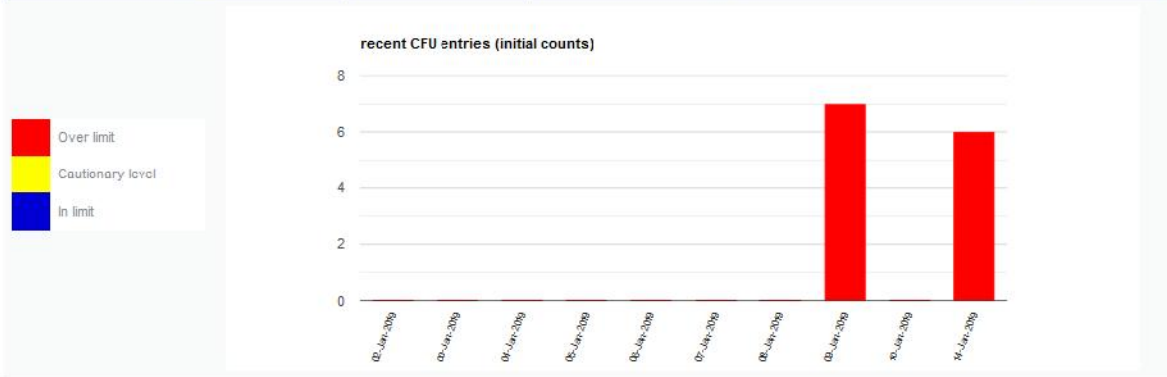
Remedial Actions:

Summary: Completed B Clean

Action	Description
checked ok	Environmental Monitoring Review
not checked	Adjacent Area
not checked	Weekly Cleaning Schedule
not checked	Device Maintenance Log
not checked	Operational Log
not checked	Staff compentencies - currency
checked ok	Additional cleaning employed
not checked	Additional EM Sampling

data entered by the user: nine, operator responsible in reporting the process was unsp, time stamp: 2019-04-01 13:46:15;

Return to tasklist

Supervison:

Each over-count event – both alerts and fails are monitored in the supervision list.

These will progress through three colour coded explanatory stages.

In the laboratory column this will be shown as: 'Incomplete'or 'With Lab Exec' or 'Complete'

In the Prevention Correction column the stages are 'Incomplete' or ' In Progress' or 'Complete'.

The supervisor can see all relevant dates, plate history and the work done.

Labwork column		Prev/correct column	
Incomplete	No work done.	Incomplete	No work done.
With Lab Exec	Lab bench has identified and counted cfu, but lab executive has yet to comment	In Progress	Corrective action has been taken, but has been marked as in progess as other work remains to be stored.
Complete	Lab Executive has reviewed lab findings – optional comments, optional grading of importance	Complete	Corrective actions have been completed.

Member rôles of the system. We suggest you view the very short online training videos – which are usually about three minutes per topic.

Pharmaceutical Staff:

For the Owner(s)

> Appreciate an overview Goldplate work flows and reporting
>
> Learn how to add new users / operators (and the difference between them)
>
> Learn how to set up the system (Locatons, Plates and Groups)
>
> Learn how to factory reset a Goldplate system (after familiarisation exercises)
>
> Unless there is a competent manager - be in a position to train staff in all rôles

For the Manager(s)

> Understand how Goldplate work flows and reporting function
>
> Learn how to add new operators (and what an operator is)
>
> Be in a position to train staff in all rôles

For Clean Room Supervisor(s)

> Understand an overview of Goldplate work flows and reporting
>
> Learn how to add new operators (and what an operator is)
>
> Be in a position to train staff in clean room operations relating to Goldplate

For Clean Room Staff

> Learn how to monitor and use the prevention and correction task list (over-count events)
>
> Learn the actions to take on discovery of over-counts

Laboratory Staff:

For the Laboratory bench Worker

> Learn how to monitor and use the Laboratory task list
>
> Learn how to action each item in the Laboratory task list

For the Laboratory Executive

> Understand the laboratory bench worker functions
>
> Learn how to use and report on the Executive task list.

Summary of Staff Functions:

Operators of the Clean Room Environment

Staff who enter CFU counts: Primary function is to read plates and enter the results correctly.

Can also:

- Add new plates to a group
- Move a plate to another group (and its data)
- Change the order in which the plates appear in a group
- Rename a plate
- See a monthly overview of the results in a group
- Print a consignment list to accompany plates to the laboratory

The Prevention Correction (clean-up) Staff

Have access to all the functions above and…

- Examine each over-count on their work-list and determine / record the preventative and corrective actions that have been taken accordingly.

Supervisors of the CFU entry and Prevention Correction teams

- Extra function in addition to above…
- Examine the progress of the laboratory work-list
- Examine the progress of the prevention correction work-list
- Supervise accordingly

Department Manager(s)

- Be knowledgeable of all functionality
- Ability to train staff to all levels
- Monitoring of Staff and Work-list
- Produce reports as required
- Maintenance of operators and their rôles

Owner

The system / department manager can make any and every change. There will be at least one of these people on the system this person has access to powerful system tools and configurations.

- In addition to all above:
- Recruit and maintain users (logins to the system)
- Department Build of plate structure
- Access to reporting and monitoring tools
- System Reset to factory default (following training / familiaisation)
- May recruit users at all levels – including extra 'Owners'

Laboratory Staff:

Bench workers:

- Monitor the laboratory task list and process:
- Confirm / Correct CFU counts
- Enter organism(s) found
- Make relevant comments

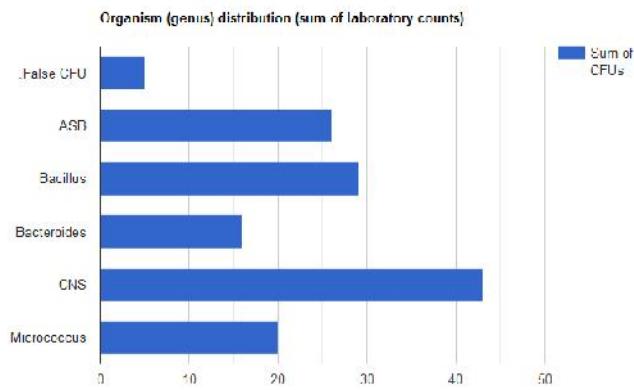Laboratory Executive – This is an optional function you may wish to employ.

- Monitor the laboratory executive task list and process
- Review bench findings
- Comment and grade on significance

Some examples of built in reporting tools:

Organism distrinution

Individual Plate Trending

Month view – and a lab result 'call-out'

HOME | ADD SYSTEM USERS | CFU ENTRY | LABORATORY | LAB EXECUTIVE | PREVENT & CORRECT | SUPERVISE | REPORTING | TOOLS | LOGOUT
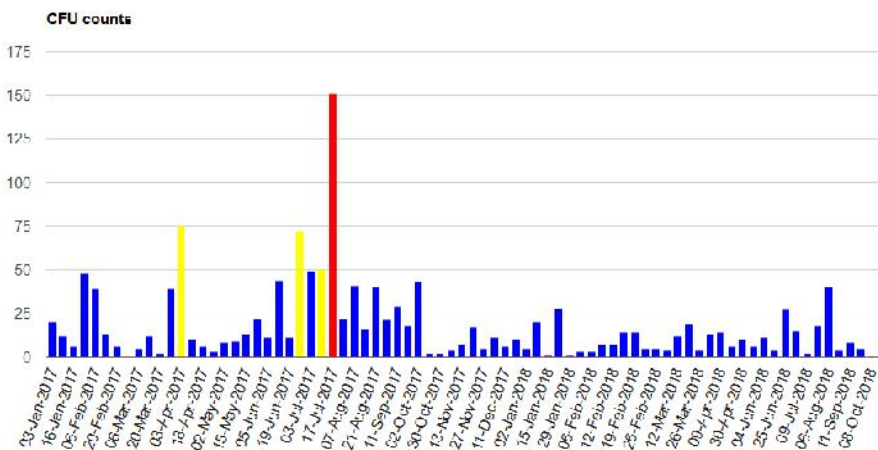
Over limit
Cautionary level
In limit

rp

All AM PM Out of hours

| | Environmental Monitoring Results | | | | | | | | rp | | | | | | | | Nov 2018 | | | | | | Session = all | | | | | |

sessional | weekly | monthly | quarterly

Lab date	Session	CFUs	Genus	Species	Lab comments
2018-11-15	am	1	ASB	ASB Sp.	No further comments added

hover any over-count to see the laboratory results (there will be a line for each organism type where found)

HOME | ADD SYSTEM USERS | CFU ENTRY | LABORATORY | LAB EXECUTIVE | PREVENT & CORRECT

Over limit
Cautionary level
In limit

Environmental Monitoring Results | asep

F1 contact isolator L Op Lh glove TSA

place the mouse over any plate prefix to see its full name

Tip: place the mouse pointer over any plate prefix to view its full name

12

Over-counts (first three weeks in July 2019 are shown)

Overcounts Summary:

Date	Group	Plate	Type	Lab CFUs	Fail limit	Warn limit	Genus	Species
Thu 19-Jul-2018	asep sessional	2 settle isolator LH hatch TSA	alert	3	5	2	CNS	CNS Sp.
Tue 17-Jul-2018	tpn sessional	F2 contact isolator L Op Rh glove TSA	fail	1	0	0	ASB	ASB Sp.
Wed 04-Jul-2018	cyto sessional	2 settle isolator LH hatch TSA	alert	1	5	2	ASB	ASB Sp.
Wed 04 Jul 2018	cyto sessional	2 settle isolator LH hatch TSA	alert	1	5	2	Micrococcus	Micrococcus Sp.
Tue 03-Jul-2018	asep sessional	F3 contact isolator R Op Lh glove TSA	fail	1	0	0	ASB	ASB Sp.

Menus available to each type of user:

Owner: All functions: may add users and alter settings.

| HOME | ADD SYSTEM USERS | CFU ENTRY | LABORATORY | LAB EXEC | PREVENT & CORRECT | SUPERVISE | REPORTING | TOOLS | LOGOUT |

Manager: All departmental functions

| HOME | CFU ENTRY | LABORATORY | LAB EXEC | PREVENT & CORRECT | SUPERVISE | REPORTING | LOGOUT |

Clean Room Supervisors

| HOME | CFU ENTRY | PREVENT & CORRECT | SUPERVISE | REPORTING | LOGOUT |

Clean Room Staff

| HOME | CFU ENTRY | PREVENT & CORRECT | LOGOUT |

Laboratory Exec (may interpret results)

| HOME | LABORATORY | LAB EXEC | LOGOUT |

Laboratory worker (lab investigations)

| HOME | LABORATORY | LOGOUT |

Features available to each type of worker (assigned through the 'ADD SYSTEM USERS' menu)

function	Lab Worker	Lab Exec	Clean Room Staff	Clean Room Supervisor	Manager (all departmental functions)	Owner
Reset own password and email	✔	✔	✔	✔	✔	✔
Use the laboratory task-list	✔	✔			✔	✔
Enter laboratory results	✔	✔			✔	✔
Give recommendations on laboratory results		✔			✔	✔
Select plates for cfu entry; save results			✔	✔	✔	✔
Amend pass counts to alert and vice-versa			✔	✔	✔	✔
Amend fail notice (keeping same cfu count)						
Add new plates to an existing group			✔	✔	✔	✔
Move an existing plate to another group			✔	✔	✔	✔
Change plate order within a group			✔	✔	✔	✔
Rename a plate			✔	✔	✔	✔
See a monthly overview of data entered by group			✔	✔	✔	✔
Produce a daily consignment list of over-counts			✔	✔	✔	✔
Use the prevention and correction task list			✔	✔	✔	✔
Enter actions for prevention and correction			✔	✔	✔	✔
Use supervision task list (lab and prev/correction)				✔	✔	✔
View progress and outcomes of lab and prev/correction				✔	✔	✔
Run organism distribution reports				✔	✔	✔
Run plate trending reports				✔	✔	✔
Produce over-count list				✔	✔	✔
Add system users (with a login invitation)						✔
View and enable/disable system users						✔
Add 'workers' and change their role						✔
Manually create locations						✔
Manually create groups						✔
Use the automated group / plate generator						✔
Change group orders						✔
Remove unwanted system generated groups or plates						✔
Download a data file of all cfu entries						✔
Alter configuration settings (see separate table)						✔
Factory reset database (password challenged)						✔

The configuration settings – available only to 'Owner(s)' in the TOOLS menu

description	Default setting	Minimum allowed	Maximum allowed	Force compliance with min/max
Organisation name	empty	-	-	No
set number of days before password expires	121	30	1095	Yes
minimum number of special characters required in p...	2	0	99	Yes
number of capital letters required	2	0	4	Yes
password: exclude common words	0	0	3999	Yes
first session label 1 text (data stored as am)	morning	-	-	No
second session label 2 text (data stored as pm)	afternoon	-	-	No
third session label 3 (data stored as out-h)	overnight	-	-	No
ISO Country Code (US UK CA AU NZ etc.)	empty	0	0	No
Timezone offset from UTC	0	-12	14	Yes
LabExec report CRITICAL Send notification email(s)	empty	-	-	No
LabExec report HIGH Send notification email(s)	empty	-	-	No
LabExec report MEDIUM Send notification email(s)	empty	-	-	No
LabExec report LOW Send notification email(s)	empty	-	-	No
laboratory: days to keep on screen	366	30	3655	Yes
lab executive: days to keep on screen	366	30	3655	Yes
prevention / correction: days to keep on screen	366	30	3655	Yes
supervision: days to keep on screen	366	30	3655	Yes
graphing: set days shown after CFU selected	14	7	180	Yes
graphing: set days shown before CFU selected	21	7	180	Yes
progress reports - Send notification email(s)	empty	-	-	No