LIGHTHOUSE
WORLDWIDE SOLUTIONS

GOING PAPERLESS IN THE CLEANROOM

Lighthouse Worldwide Solutions

Overview

The current process of using a paper-based method to count particles in cleanrooms generates vast data volumes, leading to time-consuming photocopying, signing, and filing. Human errors compound the problem. The Lighthouse ApexZ Portable Particle Counter is the solution. It offers multiple paperless options, enhancing workflow efficiency.

Precise workflows are critical in pharmaceutical settings, and ApexZ delivers. Pre-sets, sample plans, an increase in flowrate from 1CFM up to 100LPM, and grid views simplify operations. Pre-sets link predefined procedures to locations, reducing operator errors. Sample plans enforce SOP adherence and prevent common cleanroom organizational mistakes. Grid views provide real-time testing status monitoring.

In summary, ApexZ makes transitioning to a paperless cleanroom effortless, saving time, reducing errors, and enhancing data accuracy and compliance. Bid farewell to paperwork and welcome a more efficient cleanroom data management future.

What Does Going Paperless in the Cleanroom Mean?

Many years ago when particle counters were developed and their predecessors came along, over the years one major component in particle counters has always remained even when sensor technology in size shrinked from HeNe lasers to today's much smaller laser diodes the ticker tape printer has remained. In the 1980's memory was pretty small so capturing and recording large data chunks was not a luxury we have today with the advent of Solid State Drive memory advances. One terabyte is small in today's memory driven and memory fueled world. The data had to be recorded on a ticker tape which was generated from an internal printer inside the particle counter. Now that we have abilities to store and transfer data effortlessly the move to a paperless cleanroom associated with particle counters has begun. So going paperless really means the end of the labor intensive ticker tape print outs and the management and storage of that data. The lighthouse ApexZ is a great solution to going paperless effortlessly.

How Labor Intensive is the Current Particle Counter Paper Method?

Let's look at a typical 8 hour aseptic fill run which includes 65 sampling locations for non-viable sampling using particle counters. Every minute there are 65 samples (based on the update rate of the particle counter for continuous monitoring) which equates to about 31,200 data records for one day. If the aseptic filling is 7 days a week then over a week 218,400 data records for particle counts are collected. That's a lot of data to manage for 1 week just for one filling line and the supporting cleanrooms that also must be monitored. The number of daily ticker tape print outs could easily be near 670.

That's quite a lot of paper records to manage. Over a week the paper management mountain has grown to 4,690 ticker tape records. So each ticker tape record on a daily basis will need to be taken from the particle counter, photocopied as the ticker tape is on thermal paper that fades over time so each record needs to be photocopied and then signed off and filed away in a secure location. Let's say this activity takes 5 minutes per record then over a day the time needed to manage the paper records equates to about a week's labor to manage one day of records. That's probably a couple of full time positions required just to manage the data. We have not even touched on the level of risk involved and the human error factor in handling large volumes of data manually.

Basic cleanroom operation for an 8 hour pharmaceutical injectable fill operation:

- **65 locations to particle count daily**
- **480 tests for 8 hours in grade A**
- **90 tests for 9 hours in grade B**
- **100 tests for 2 hours in grades C&D**
- **670 particle count sample ticker print-outs**
- **1 EM manager, 5 technicians**
- **>5000 data entries required**

Is There an Easier Way to Manage and Organize all of this Data?

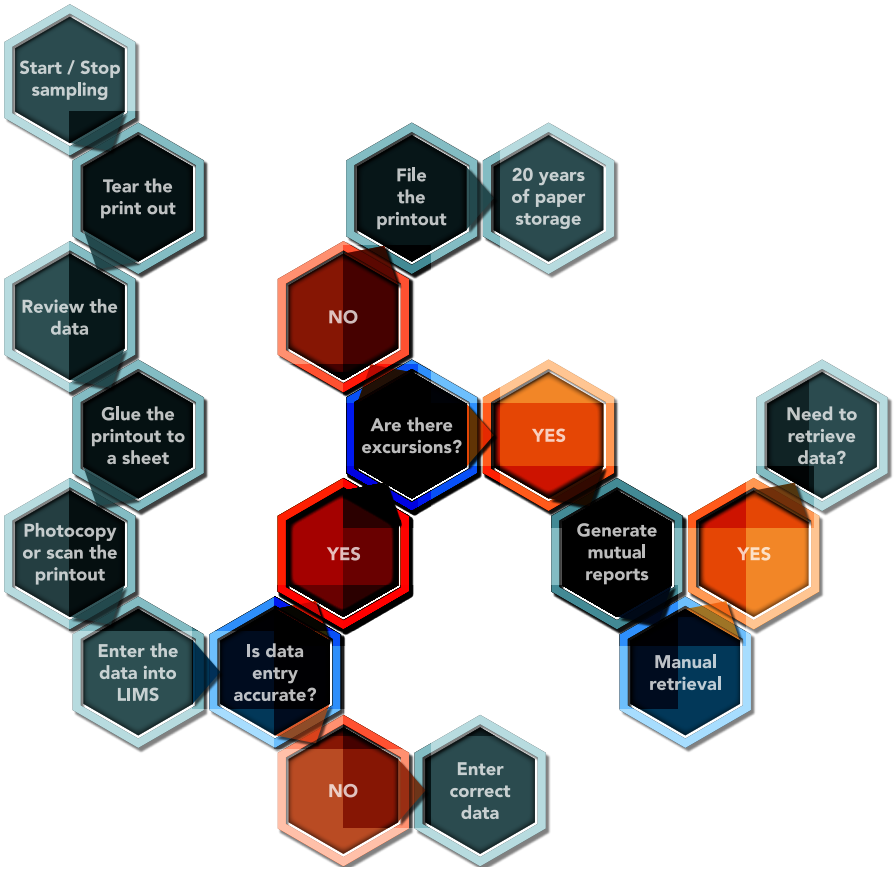
The ApexZ was built for paperless data management and has several paths to a paperless management system as well as enhanced features for workflow. If we look at a typical Pharma workflow scenario, we see that process problems may arise if the workflow is not managed correctly and in sequence.

Each particle counting test must:

- Follow the prescribed SOP for test protocol
- Be taken in sequence location to location
- Configured to take different required air volumes from A-B-C-D room requirements
- Produce a manual ticker tape of the data; with a minimum of 5 data tags
- Evaluate for pass/fail criteria excursions must be documented for rationale and samples taking again

Remember: What could go wrong?

- Do you have each ticker tape record?
- Did each ticker tape get scanned & signed?
- Did you document excursion reasons?
- Did every test follow the SOP?
- Did every test occur in the time sequence?
- Did you miss any test locations?
- Was the all the data transcribed into LIMS?
- Was all the data transcribed accurately?



Decision tree for paper sampling

How Can the ApexZ Organize and Manage Workflow?

Common cleanroom errors in taking APC samples in the cleanroom:

- **Test location not labeled within APC instrument**
- **No pre-defined/validated sampling protocol in the APC instrument**
- **APC instrument provides more data than is required by the sampling procedure**
- **APC instrument must be configured at each location to run samples**
- **Alarm/Alert limits are manual**
- **APC instrument has fixed units of measure, but clean room operates in SI and imperial units depending upon customer needs**

ApexZ was Designed to Organize Cleanroom Workflows:

Pre-Sets

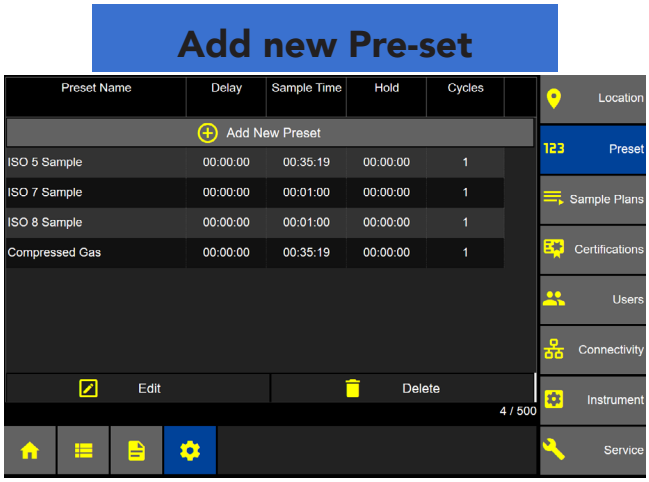
The ApexZ has Pre-sets, Sample Plans and Gridviews to enable cleanroom sampling workflows to be easily setup and configured.

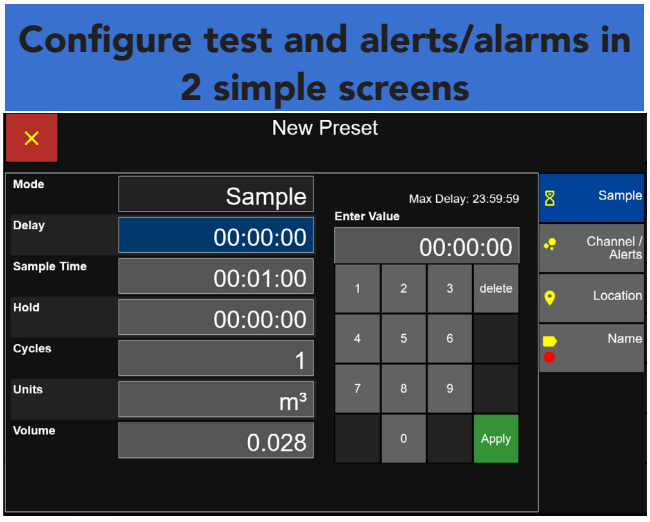
Pre-set = a predefined APC sampling procedure.

A Pre-set can be assigned to any location in the cleanroom and that preset can be locked and linked to that location. Therefore the operator has a set of predefined procedures locked into the ApexZ with the right SOP test embedded. This mitigates against any operator error in using the wrong SOP test in the wrong room or location.

Presets can be easily reassigned to any location so reconfiguration per location or room is no longer necessary. Alert and Action alarm settings are easily enabled based on internal SOP's and these settings are locked into each location.

Apex Z pre-set workflows eliminates and reduces common errors that occur during APC sampling in the cleanroom, by enabling the users to have validated tests – configured specifically to each location in the clean room operator errors are eliminated.





Value Proposition of Pre-set workflows

Common cleanroom errors in taking APC samples in the cleanroom:

- **Test locations not labeled within APC instrument**
- **No pre-defined/validated sampling protocol in the APC instrument**
- **APC instrument provides more data than is required by the sampling procedure (pre-set)**
- **APC instrument must be configured at each location to run samples**
- **Alarm/Alert limits are manual**
- **APC instrument has fixed units of meassure, but cleanroom operates in SI and Imperial units depending on customer need**

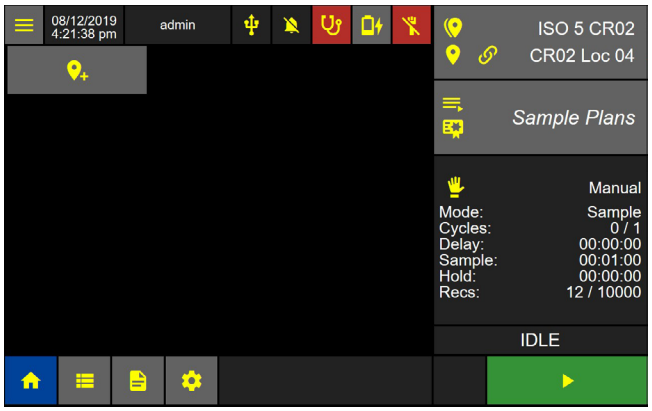
These common cleanroom errors are eliminated by PRESETS

"Validated Presets can be assigned by a manager and the ApexZ can be given to an operator to execute the cleanroom testing without gathering invalid data location to location."

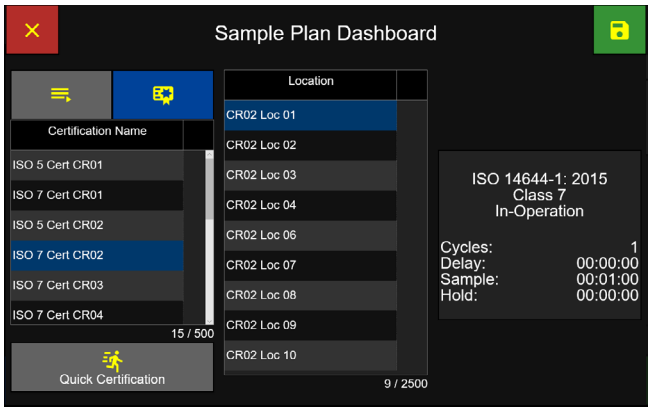
Sample Plans

Sample Plan = organize the entire cleanroom workflow

The ApexZ's sample plan workflow tool enables EM manager and technicians to validate the instrument and cleanroom to SOP specific test plans to ensure SOP adherence and data compliance.



1 click to load sample plan with user defined controls



Easily select any sample plan for the operator or entire cleanroom workflow

Common cleanroom organization/workflow errors:

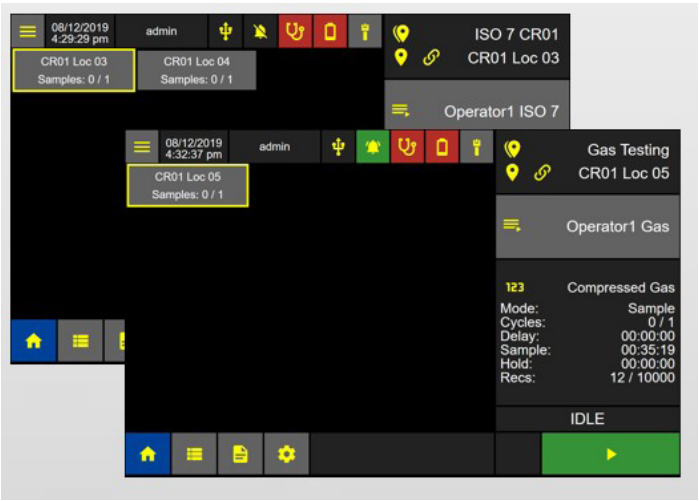
- **3 tech's take all tests in the clean room, but 4 locations missed**
- **Technician misses a test location**
- **Technician tests locations out of sequence from the SOP**
- **Alarm condition requires a retest, and SOP are not followed**
- **Operator moves between Grade A & B rooms and incorrect SOP applied between rooms.**

With a Sample Plan, each operator has a locked/secure test plan in each instrument for each cleanroom requirement. With the ApexZ Sample Plans, operator sample errors can be eliminated as each operator will have a predefined sample plan to follow with all the sampling configurations locked in with each location.

For example, below Operator 1 is assigned to test an ISO 7 environment with 2 locations in CR01 and a Gas sample point in CR01.

Operator 2 is assigned to test an ISO 5 and ISO 7 environments with 5 locations each in CR02.

Operator 1 - Assigned ISO 7 room with 2 locations & gas testing



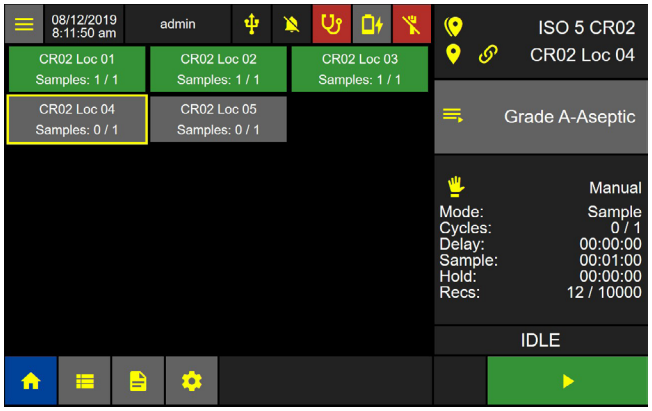
Operator 2 - Assigned ISO 5 & ISO 7 room with 5 locations

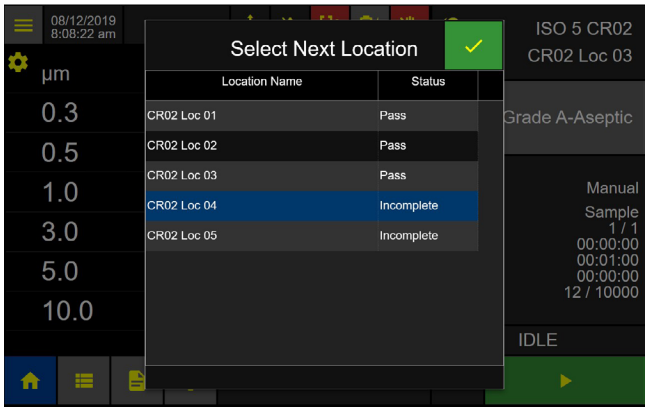
Sample Plans mitigate against operator sampling errors.

Grid View

Grid View = enables the testing status.

With Grid View function available on the ApexZ operators can easily see the current sampling status. Locations are in a box format with the details of the location contained within including the number of samples taken at that location. A green box means the sample is completed at this location and has passed the test criteria.

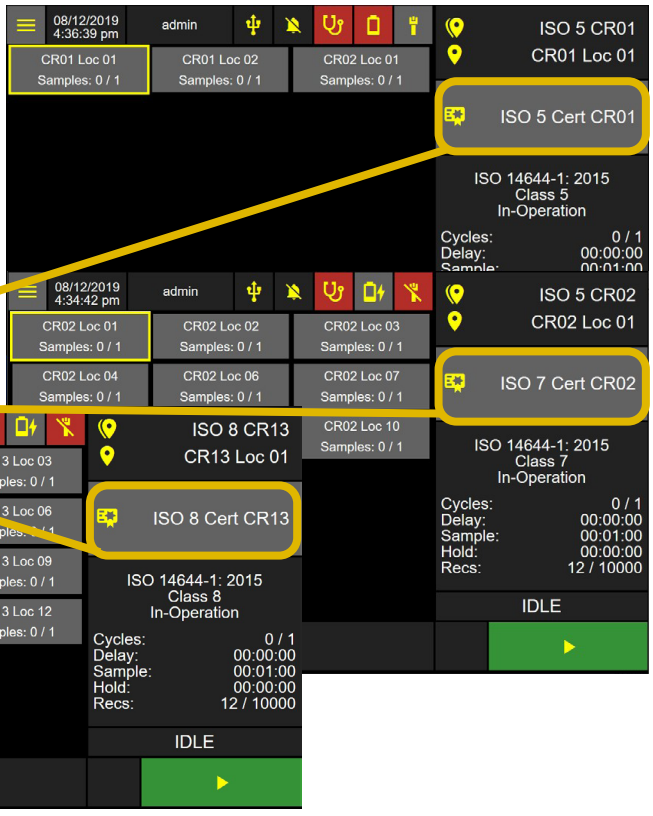




Grid View Color Status:

- **Yellow boarder = current location**
- **Green Background = sample completed with no warning or alarms exceeded**
- **Blue background = currently sampling**
- **Grey background = location not yet sampled**
- **Red background = sample completed but alarm threshold particle count was exceeded or if instrument was in fault for laser, flow or calibration due date**

"The most intuitive Sampling Workflow process ever designed to keep you updated on the sampling status with a quick glance at the screen."

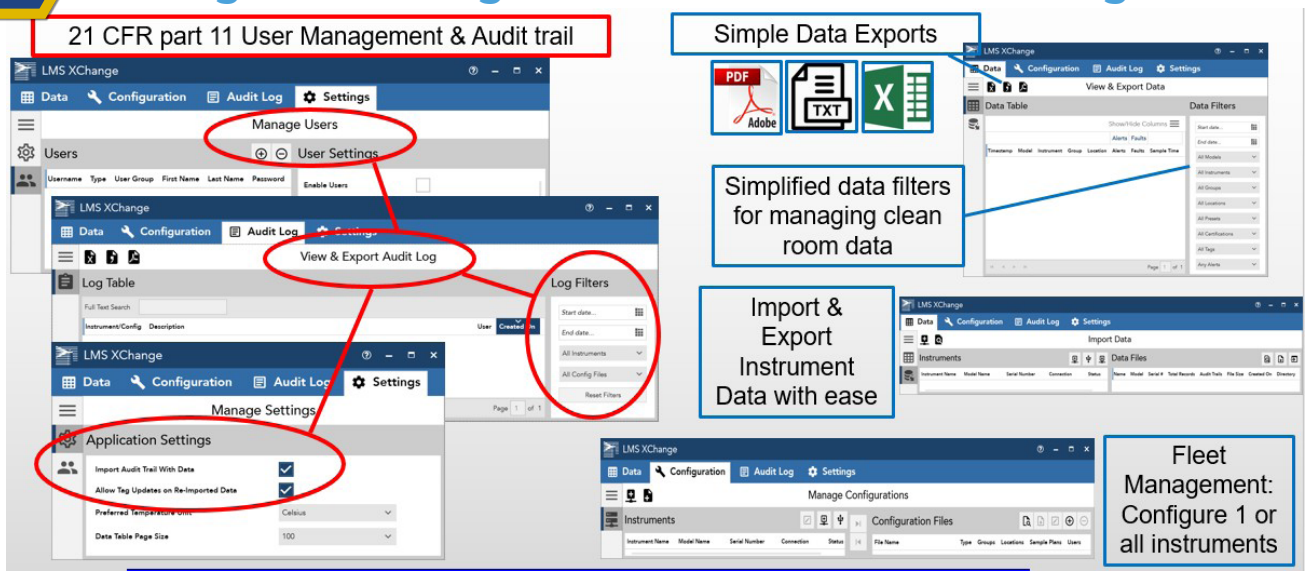


Clean room certification made easy – switch between ISO 5, 7, 8 sample plans with ease – Grid View enables walk away time to perform other tasks and know where the next test is at

ApexZ - 4 Paths for Paperless Data

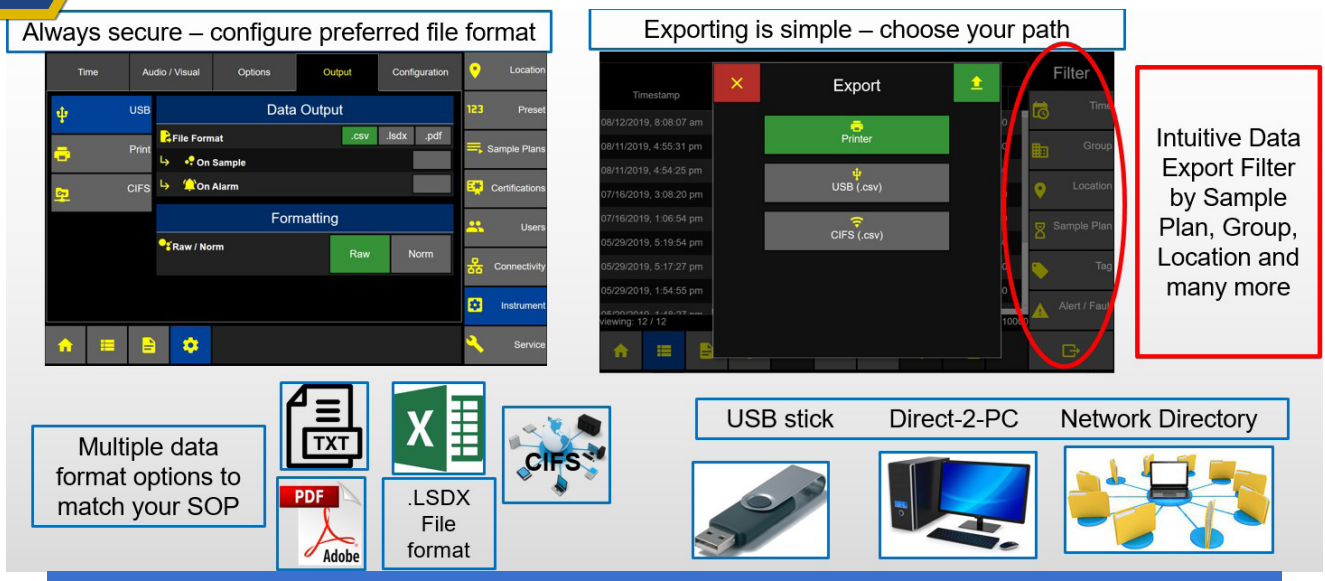
Now you have all the data, what are the data management options available to go paperless? With the ApexZ, you have multiple options for paperless data management. Let's look at each option.

1 Using LMS Xchange – Intuitive 1 click data management



Paperless intuitive secure data management - no training required

2



ApexZ enables direct secure data transfer anywhere you want

3 Lighthouse Monitoring Systems - Real-time data management systems

Real Time Monitoring Systems

LMS Pharma | LMS Pro | LMS Express | EMS

Manage a fleet of APEX Z portables across multiple clean rooms

Manage a group remote sensors & portables for clean room monitoring

Manage all clean room monitoring parameters – viable, non-viable, RH,T, AV, DP Configured to you needs

- LMS Express – out of the box simple, ready to install in any clean room for managing particle counter data
- LMS Pharma – 21 CFR custom configured to your exact real-time clean room monitoring SOP and specifications
- **LWS customers with LMS Express & Pharma class A rooms can add APEX Z's to their system for class B & C environments NOW!!!!**

LMS Express

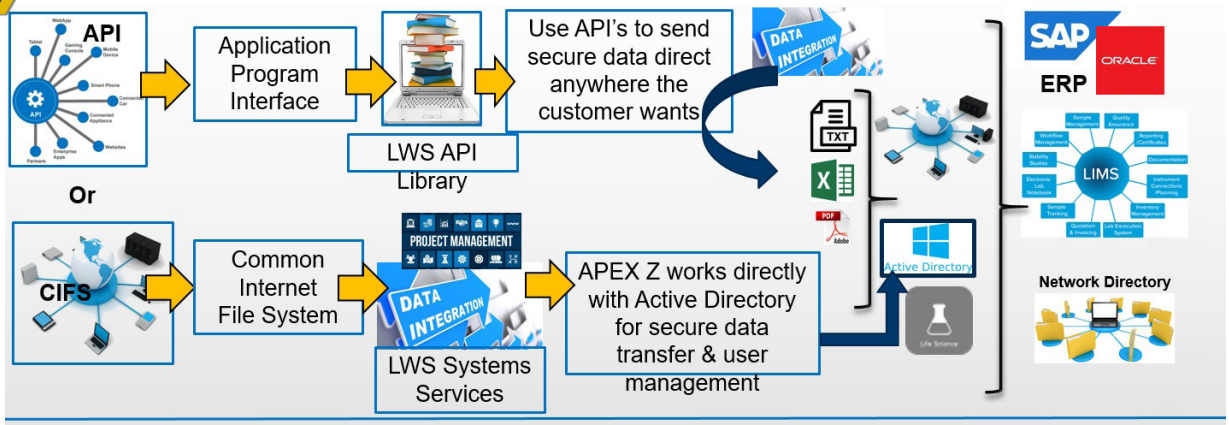
LMS Pharma

DATA INTEGRATION

PROJECT MANAGEMENT

Lighthouse offers multiple software solutions to automate and make clean rooms paperless and error free

4 Lighthouse Systems services will integrate API & CIFS



Lighthouse systems services will integrate API & CIFS solutions

Project Management Services:
We will coordinate and ensure timely install & validation of all instruments & data transfer needs

PROJECT MANAGEMENT

Data Integration Services:
Automated data transfer into your existing IT environment to meet both EM, Quality and IT department needs.

DATA INTEGRATION

Data Validation Services:
Develop validation protocols for all aspects of data transfer in your IT environment.

Lighthouse systems services will integrate API and CIFS solutions