

EMPQ Preparedness Checklist



AZZUR GROUP
From Discovery To Delivery™



- ☐ Protocol signed
 - **EMPQ, sampling SOP's, gowning, cleaning, packaging/shipping of samples**
 - **Cleanroom temperature/humidity controls/monitoring equipment**
 - **Recording/calibrated/validated and within specifications prior to start**
- ☐ Personnel trained
- ☐ Gowning, cleaning, sampling, EMPQ, packaging of samples, facility safety training
- ☐ Purchase/rental/calibration of sampling equipment
 - **Viable air sampler**
 - **Particle counter**
 - **Surface samplers**
- ☐ Method of sterilizing air sampler heads
- ☐ Personnel/equipment flow sop
- ☐ Sample maps approved/color coded
- ☐ Sufficient personnel available during:
 - **Weekends**
 - **Holidays**
 - **After hours**
 - **Extended hours**
- ☐ Gowning validation completed
- ☐ Media growth support and sterility testing completed
- ☐ Particle counters programmed and verified

EMPQ Preparedness Checklist Cont.



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- ☐ Acceptance criteria set/rooms graded and/or classified
- ☐ Non-conformance and/or deviation procedures in place
- ☐ Sample form, cleaning form, temp/humidity pressure forms approved for use
- ☐ Cleanroom certified
- ☐ Cleanroom cleaning scheduled around EMPQ sampling times, determine time needed to clean and dry the facility based on:
 - **Contact time**
 - **Number of rooms**
 - **Number of cleaning sessions**
- ☐ Parameters regarding analysis and study determined
- ☐ Media, volume, locations, incubation, level of analysis, frequency, activity level
- ☐ Equipment charged
- ☐ Transportation, packaging of samples to laboratory – purchased/defined materials ordered and approved for use:
 - **Media**
 - **Sample bags**
 - **Gowning supplies**
 - **Gloves**
 - **Ice packs**
 - **Particle counter paper**
 - **Disinfectant**
 - **Cleanroom cleaning supplies**
 - **Sterile wrap or autoclave bags**
 - **Purge filter**
 - **Wipes**