Structural Integrity Associates, Inc.®

RISK MANAGEMENT FOR PHARMACEUTICAL MANUFACTURING

THE PROBLEM

Pharmaceutical manufacturing plants sometimes experience failure of fixed assets due to unanticipated or unmonitored damage from mechanisms including:

- Thermal fatigue
- High cycle fatigue (vibration)
- Stress corrosion cracking
- General corrosion (including rouging)

Also, design inadequacies related to design basis and beyond design basis events such as severe weather events and seismic loadings can impart damage. This damage, that may eventually result in failure of structures, systems and components, can result in costly business interruption. Moreover, if the failures are not properly understood and mitigated, repeat failures are possible.

THE SOLUTION

Structural Integrity Associates, Inc. are experts in the prevention and control of structural and mechanical failures. Our expertise is based on 30+ years of history in applying a blend of the following disciplines:

- Non-destructive testing;
- Material science; and
- Engineering analysis

Our non-destructive testing involves advanced methods of damage detection and characterization employing and innovating around the latest technologies including linear phased array ultrasound, dynamic pulsed eddy current, and guided wave testing. Structural Integrity has developed and deployed many first-of-a-kind non-destructive testing technologies and techniques in the field.

Our material science expertise is based on a foundation of understanding materials, their operating environments and the likely causes of degradation based on research and experience. Resources include our materials science center in Austin, Texas, and many metallurgists and materials scientists experienced in failure analysis, damage progression and damage mechanism mitigation.

Our engineering analysis capabilities stem from our experience in developing and applying advanced finite element models to simulate material and structures behavior to accurately quantify damage progression and remaining life (with or without repair or mitigation), or capacity to withstand environmental conditions. When properly combined and applied, these disciplines can be used to identify, quantify and mitigate risks to pharmaceutical manufacturing that averts costly business interruption.

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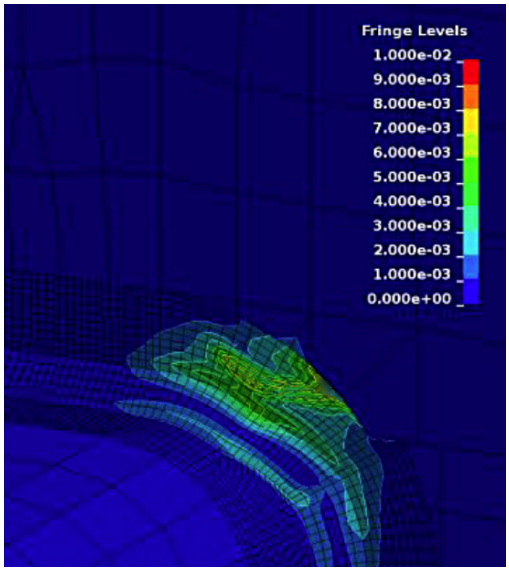
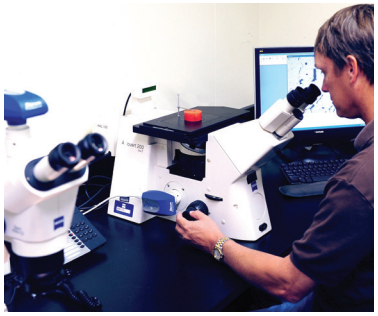
REPRESENTATIVE PHARMACEUTICAL PROJECT PROFILES

Sterilization Chamber Fatigue Cracking – A large 316SS chamber with external carbon steel stiffeners experienced cracking due to thermal fatigue from cyclic process heat and vacuum conditions. Field exams were conducted using eddy current, material samples were extracted and laboratory failure analysis was conducted that confirmed fatigue cracking. Subsequently, finite element modelling was used to confirm high stress locations as well as confirm a mitigative repair design to the chamber's stiffener design. Lastly, field repair procedures were developed, repair oversight was provided and inspections of the repair were conducted.



Sterilization Chamber Fatigue Cracking Analysis



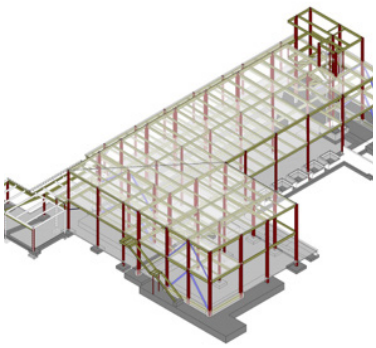
Microcracking in Process Vessels – Based on end-product contamination from biological activity in micro-cracks in a 316SS mixing tanks, Structural Integrity performs ongoing, periodic inspections of process mixing tanks for the presence of micro-cracks. An inspection protocol using non-contact eddy current technique was developed and is deployed for the inspection. Field oversight of weld repairs to resolve identified micro-cracks is provided as part of the scope of services.

Various Systems Evaluations using Non-Destructive Testing – Piping systems including those for glycol, plant steam and condensate, and refrigerated water supply and return were examined and screened using guided wave testing. Local ultrasonic inspections were conducted at unscreened locations (i.e., where localized corrosion damage potential was identified). Over 1000 feet of piping was inspected without need for insulation removal, except at collar installation locations and potential damage locations. Once local damage was characterized, API-570 based remaining life calculations were performed.


Nondestructive Examination of Waste Tank

High Cycle (Vibration) Fatigue – A piping resonance condition caused a branch line failure. Modifications were proposed to add mass to a flange set to shift natural frequency away from resonance and the branch line connection was redesigned to eliminate a high bending moment at the connecting weld. The proposed modifications were confirmed by finite element analysis modelling, and subsequently implemented by others. Once complete, the configuration was instrumented and the problem was confirmed to be resolved.


High Cycle Fatigue (Vibration)



Design and Construction Support – Structural Integrity was retained to design and analyze new concrete and steel systems, evaluate existing systems for specified loading and develop structural designs for support of nonstructural elements. Services included the evaluation of impacts of large process equipment and supporting systems on the existing building structure and development of appropriate methods for resisting seismic loading. Given tight project constraints, creative solutions were required which utilized the project team's deep understanding of building code requirements and their intent.

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for more information on our services.