TOC Recovery, Microbial Evaluation, and Cleaning **Evaluation**

Surface Roughness Sampling Study

O Confidential Client

PROJECT DESCRIPTION

This surface roughness study was performed at the Hyde Analytical Laboratory using a Sievers M9 Analyzer and an EnSURE Touch Luminometer.

The impact of stainless-steel surface roughness on cleaning activities was investigated through evaluating soil cleanability, surface swab recovery of process residue, and reduction of microbial surface contaminants.

STUDY OVERVIEW

Small-scale cleanability evaluation, microbial evaluation, and TOC swab sampling evaluation to evaluate the impact of stainless-steel surface roughness on cleaning activities at the manufacturing and filling facilities at the client site.

SCOPE AND DELIVERABLES

Used small-scale simulated cleaning cycles representative of the cleaning chemistry at full scale to assess cleanability via visual inspection, a rapid microbial method, and TOC swabbing.

Small-Scale Cleanability Evaluation

- Used an agitated immersion system and bracketed cleaning methodology to determine impact of surface roughness on soil cleanability
- · Evaluated cleaning endpoints using visual inspection of coupons

Microbial Evaluation

 Evaluated remaining microbial load on coupons of varying surface roughness following cleaning by using a rapid microbial method to detect remaining microbial contaminant Escherichia coli K-12

TOC Swab Sampling Evaluation

- Evaluated remaining Total Organic Carbon (TOC) on coupons of varying surface roughness following cleaning by using a verified TOC method and swab sampling
- Compared recovery values across roughness levels

SOLUTIONS, RESULTS AND ACCOMPLISHMENTS

- Generated data to demonstrate that surfaces of varying roughness at full-scale can be cleaned using the cleaning chemistry employed at full-scale.
- Produced recovery data to show that swab sampling recovers soils at varying surfaces roughness.
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