Further, strategic sustainable change requires a systemic approach of building awareness, checking for motivation, assessing abilities, and creating opportunities. From this perspective, workplaces need to change if we want our workers to remain safe. By implementing the use of OD, we ensure that our goal of protecting the health of workers is met.

Results: Industrial hygienists evaluate workplaces looking for potential overexposure environments. We follow exposure assessment guidelines and OSHA regulations. We use the results of these evaluations to recommend changes at the source of the exposure, but we don't look for possible organizational or departmental changes that could minimize the potential for overexposure throughout the organization. Adding OD tools to the IH toolbox provides the industrial hygienist with tools to maximize protection from the organizational level. OD tools focusing on Appreciative Inquiry and the Intentional Change Theory provide organizations with the ability to build strong departments and to obtain the buy in from employees on any proposed changes. These tools and a sustainable change process help the industrial hygienist to go beyond the immediate location of the possible overexposure to the department, the plant, and the organization.

Lessons learned: The field of OD offers a wide variety of tools for creating strategic sustainable change. These tools are beneficial to the industrial hygienist's toolbox by giving them the ability to affect sustainable changes in the workplace to attain our goal of protecting the health of workers.

CS-402-13

The Quantification of Free Drug and Antibody Drug Conjugate (ADC) Molecules **Collected During Surface Industrial Hygiene** (IH) Monitoring Procedures

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Situation/Problem: Surface cleanness monitoring is an important part of Industrial Hygiene (IH) procedures. Surfaces in antibody drug conjugate (ADC) manufacturing facilities may be contaminated with free drug (payload), active forms of conjugated drug, or a mixture of both, depending on the type of processes undertaken in the facility.

Resolution: IH monitoring of surfaces depends on successful surface wipe sampling procedures, protection of biomolecules from degradation and sampling media adsorption during transportation and storage, as well as effective fit for purpose validated analytical methods.

Results: Validated surface sampling procedure and immunoassay methods for quantification of free maytansinoid (competitive EIA) and antibody conjugated maytansinoid (double-antibody sandwich ELISA) collected on the same surface sample will be presented. The importance of immunoassay interferences in surface swab samples which can often occur due to trace contamination by cleaning agents will be emphasized.

Lessons learned: The importance of removing cleaning agents from surfaces and the verification of this action e.g., by pH or oxidation monitoring, before surface sampling is undertaken should not be overlooked as the continuing presence in the sample can lead to the destruction of the analyte and disruption of immunoassays. However, some contamination

of the surface wipe sample can be tolerated with the use of a stabilization buffer (into which samples are placed during transport to the testing laboratory). Selection of an appropriate swabbing solution is critical to ensure that free drug (payload), active forms of conjugated drug, or a mixture of both can be captured by the swabbing media. The payload and biomolecule component of the ADC often require different solvents. Systematic planning of extraction and immunoassay steps can generate simple, effective immunoassays to accurately quantify the ADC and components.

SR-402-14

Comparison of Active and Passive Sampling Methods for Formaldehyde in Pathology/Histology Labs

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Objective: The purpose of this study is to compare formaldehyde concentrations between active and passive sampling methods.

Methods: One pathology and one histology lab voluntarily participated in the present study. In each lab, personal and area exposure measurements were collected using sets of active air samplers (Supelco LpDNPH tubes) and passive (diffusive) badges (ChemDisk Aldehyde Monitor 571). At the pathology lab, samples were collected in two campaigns, 15 personal and 10 area sample pairs in one and 21 personal and 4 area sample pairs in the other. At the histology lab, 13 personal and 3 area sample pairs were collected. Participants were lab personnel who handled formaldehyde solution and personnel who did not, but, were in close proximity. Samples were analyzed by the NIOSH contract laboratory according to NIOSH method 2016 for active samples and OSHA method 1007 (using the manufacturer's updated uptake rate, which is different to that cited in the OSHA method) for passive samples.

Results: All active 8-hr time-weighted average (TWA) exposure measurements, which ranged from 0.004-0.25 ppm (median 0.04 ppm), showed compliance with the OSHA PEL (0.75ppm), but not with the lower NIOSH REL (0.016 ppm), Passive TWA exposure measurements, which ranged from 0.01-1.98 ppm (median 1.19 ppm), showed > OSHA PEL. The median of concentration ratios (passive/active) was 1.19 (range: 0.27-17.28) for all data and 1.16 (range: 0.27-6.58) after removing four outliers using Cook's distance method. The regression analysis of log-transformed data (Ho: Slope (b)=1) indicated statistically no significant difference of concentrations between active and passive samples for all data (b=0.88 with adj. R²=0.616), but a significant difference was detected for the data without outliers (b=0.88 with adj. R^2 =0.785). In addition, statistical differences were observed from the comparison of exposure measurements between the active and passive samples (all p-values < 0.05) both with and without outliers.

Conclusions: The regression analysis test result without outliers and the comparison of means indicated that there is bias between the methods. The small sample loading on the passive sampler and/or the uptake rate used may have contributed to this bias. The higher concentrations shown by the passive badges result in a more conservative assessment of risk, but the difference between methods lead to a different conclusion with regard to legal compliance in this situation.

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