Qualification of Impurities, Degradants, Residual Solvents, and Leachables in Pharmaceuticals

Impurities (from either materials intended to be part of the process of making a drug or formulating it), degradants (unintentionally formed by unintended reactions after the drug substance or product is produced and prone to increase in quantity over time due to instability of the product under conditions of storage), and residual solvents (purposely added to the synthesis product to facilitate synthesis, formulation, or dosage form production—always liquids of some degree of volatility) can become part of a drug product or substance in multiple ways. But the extent of their presence is now strictly governed by a series of International Conference on Harmonisation (ICH), U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMEA) guidelines. These ICH guidelines call for these materials to be present at levels no greater than in product specifications and (because they serve no functional purpose in the drug) are both to be kept to a practical minimum and must be qualified for safety at the highest specification levels under the assumption of maximum potential patent use of the drug (and, therefore, exposure to the

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Edited by Shayne C. Gad