Is there a deliberate (scientific, statistical or other) reason why Q3A (R2) differs from Q3B (R2) concerning the decimal place reporting requirements for impurities/degradation results less than 1.0%?

There is no significant difference in the recommendations for reporting impurities in New Drug Substances/Products. The FDA Guidance for Industry, Q3A Impurities in New Drug Substances (June 2008) contains recommendations for reporting impurities in new drug substances produced by chemical syntheses. These impurities are classified as: Organic impurities (which includes degradation products); Inorganic impurities; or Residual Solvents. Regardless of the type of impurity, this guidance recommends reporting the impurity content of batches: "Below 1.0 percent, the results should be reported to two decimal places (e.g., 0.06 percent, 0.13 percent)..."

The FDA Guidance for Industry, Q3B Impurities in New Drug Products (June 2006) contains recommendations for reporting *only* those impurities in new drug products classified as *degradation products*. This guidance recommends reporting the degradation products, content of batches: "Below 1.0 percent, the results should be reported to the number of decimal places (e.g., 0.06 percent) in the applicable reporting threshold..." In some instances, the "applicable reporting threshold" for *degradation products* may not be to two decimal places and should thus be reported accordingly.

The difference in reporting recommendations between Q3A and Q3B is primarily due to the timing of discussions at the International Conference on Harmonization (ICH). Because the difference is considered insignificant, re-opening International negotiations to attempt reconciliation is not a priority.