


## To whom it may concern

### Regarding: Elemental impurities in cell culture products

The International Conference on Harmonization (ICH) Q3D guideline for elemental impurities defines a Permitted Daily Exposure (PDE) for each element of toxicological concern.

According to the Q3D guideline scope, "The guideline applies to new finished drug products (as defined in ICH Q6A and Q6B) and new drug products containing existing drug substances." Cytiva does not manufacture finished drug products but understands that cell culture products may be used in the manufacture of finished drugs and drug products.

It is hereby stated that Cytiva cell culture products do not have elements, as defined in ICH Q3D Elemental Impurities Guidance for Industry, added as catalysts or reagents in the manufacturing process. Because some of these elements are required for cell growth, raw materials containing them may be added in trace amounts as per product formulations. As such, very low levels of some of these elements may be present in some finished cell culture products.

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