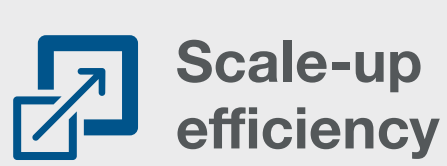


# What's causing variability in your formulation?

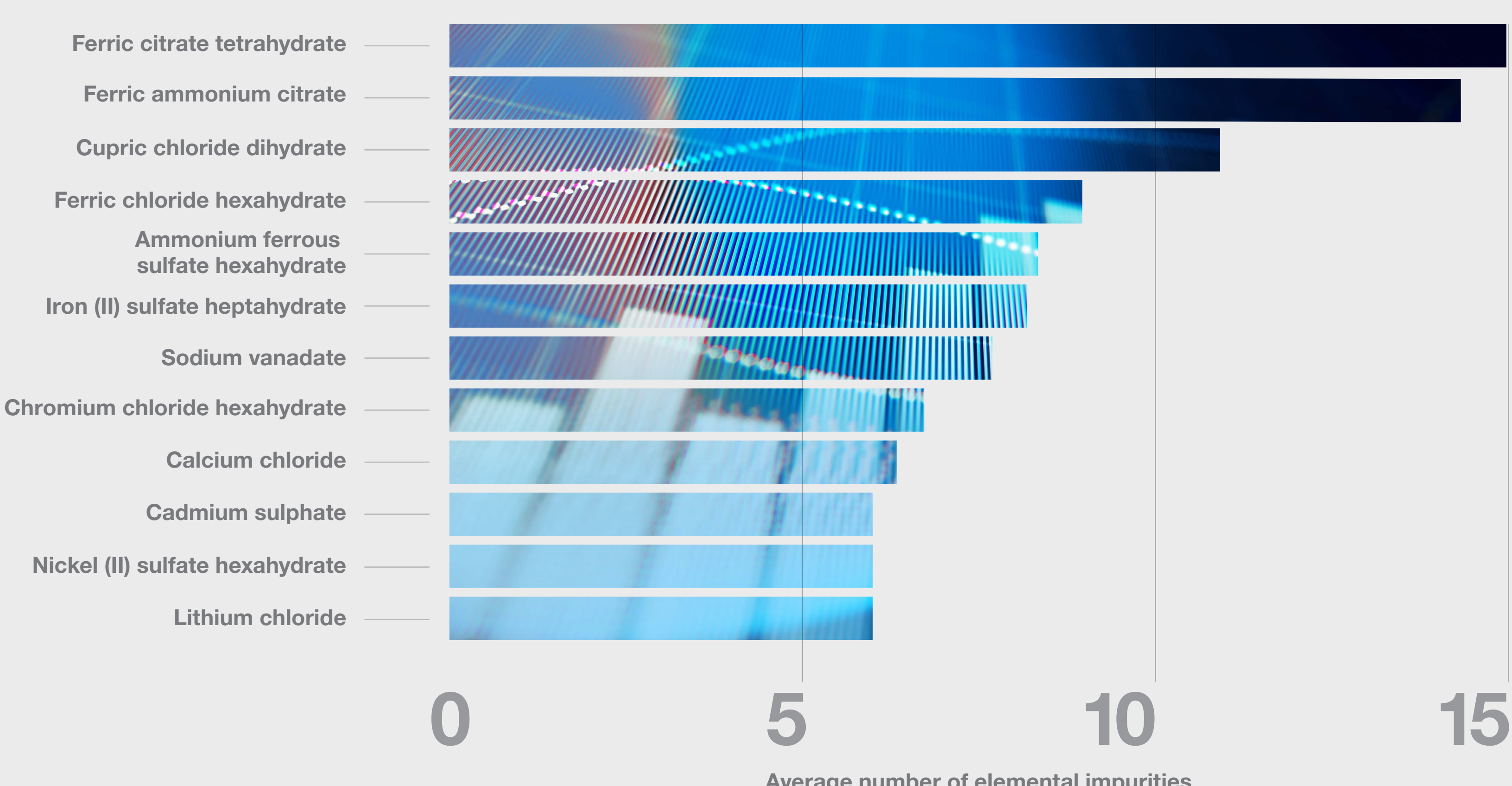
As the identity and purity of raw materials impact many aspects of a cell culture media formulation, it is vital that the composition of incoming raw materials is continuously monitored and that variability is immediately investigated. Some raw materials are more commonly associated with variability than others. Knowing which raw materials most commonly contain unexpected trace elements will help to reduce the likelihood of lot to lot variation causing costly delays to your process. Find out if you have any high-risk raw materials in your formulation and how to successfully characterize them.

## WHY IT MATTERS

Raw material/trace element variability can cause potential negative effects on:



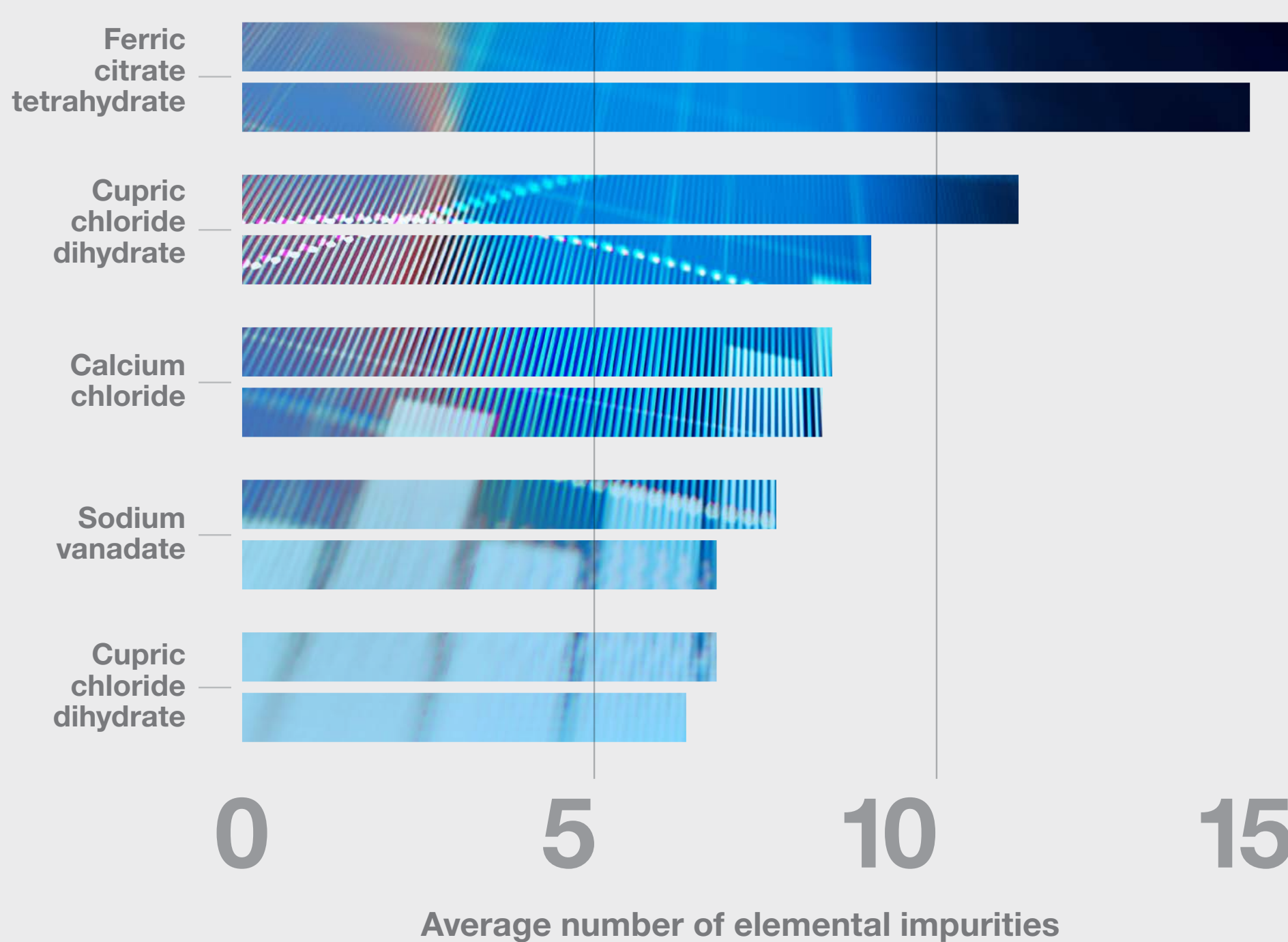
## WHICH RAW MATERIALS TEND TO HAVE THE HIGHEST AVERAGE NUMBER OF UNEXPECTED ELEMENTS?



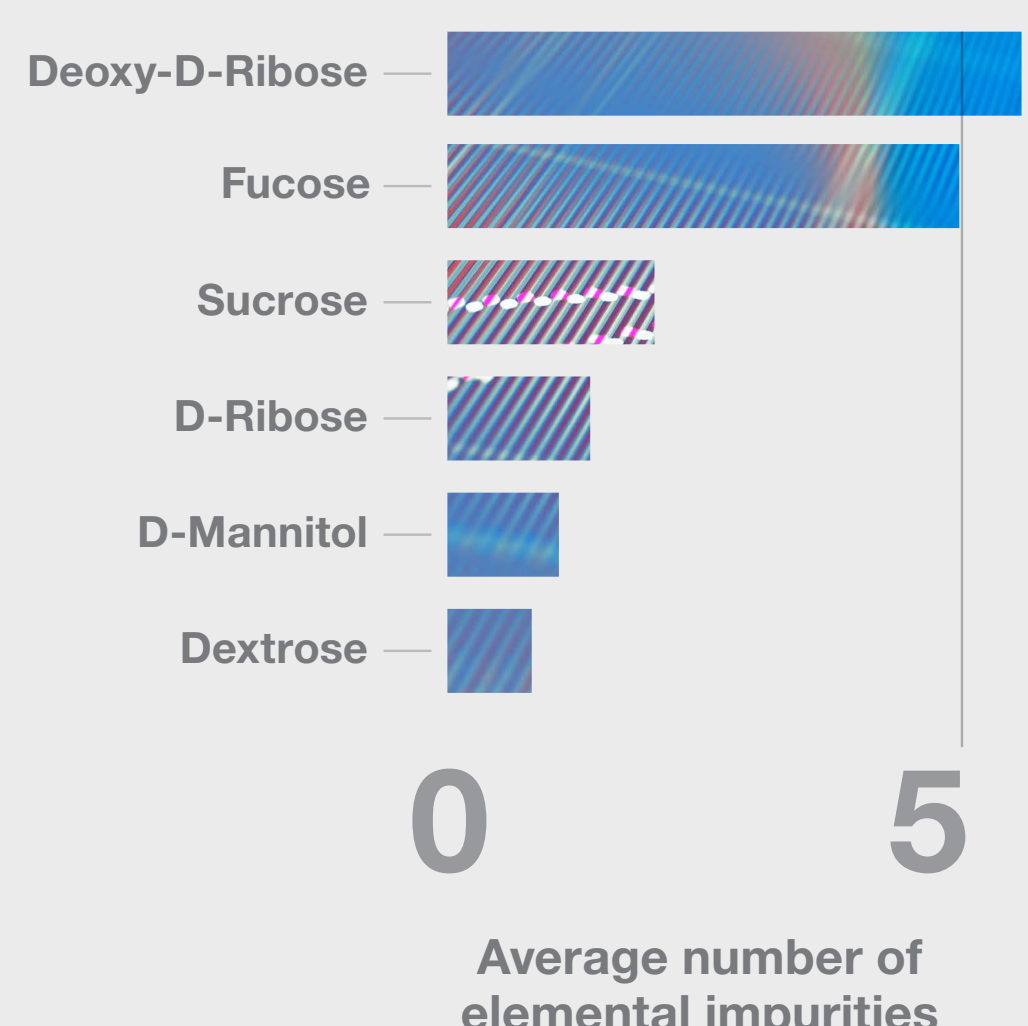
Iron salts are more likely to contain a higher number of unexpected elements, with ferric citrate tetrahydrate having on average 15 elemental impurities.

## WHICH TYPE OF RAW MATERIAL COMPONENT IS MOST LIKELY TO CONTAIN UNEXPECTED ELEMENTS?

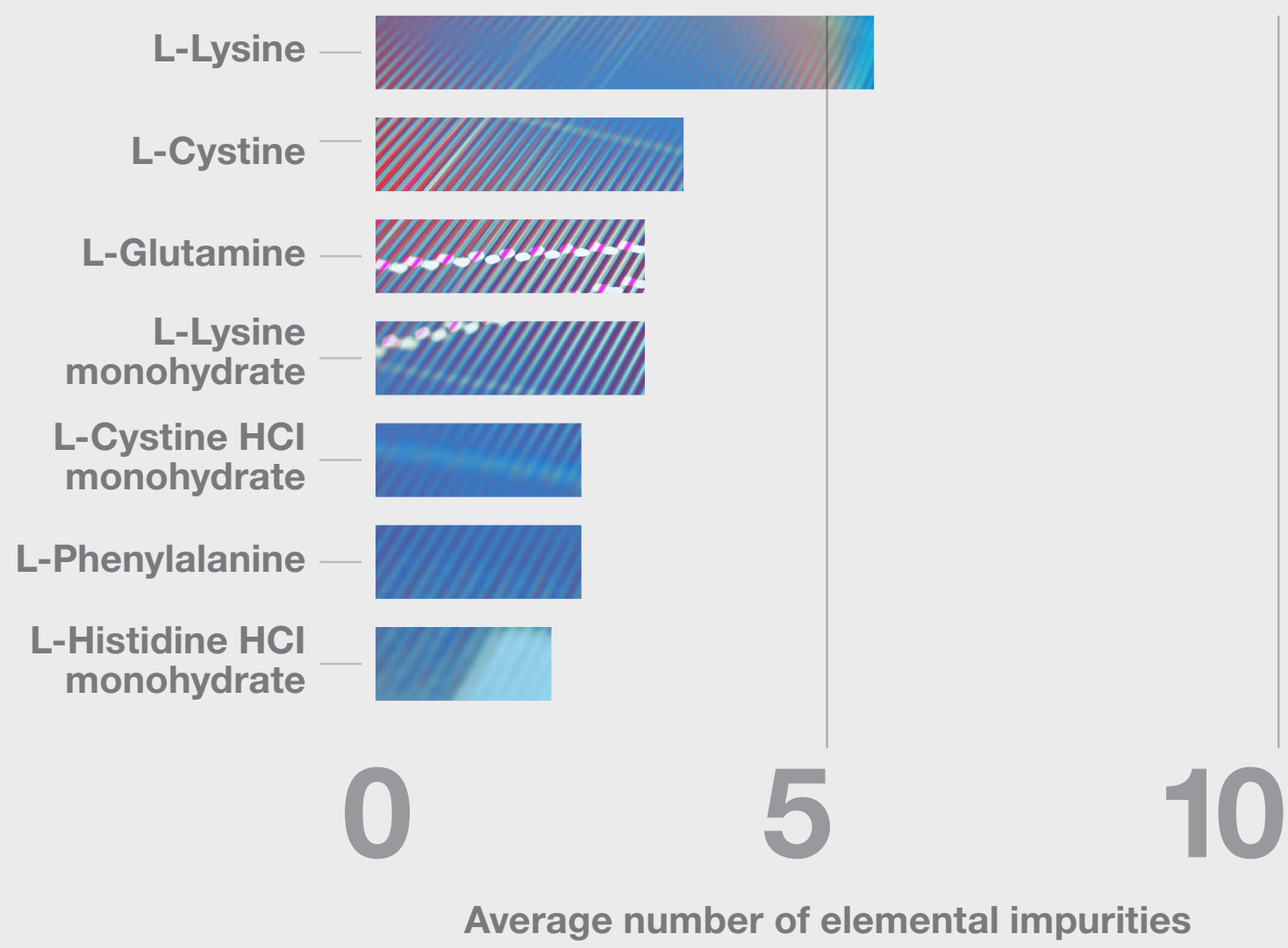
### Salts



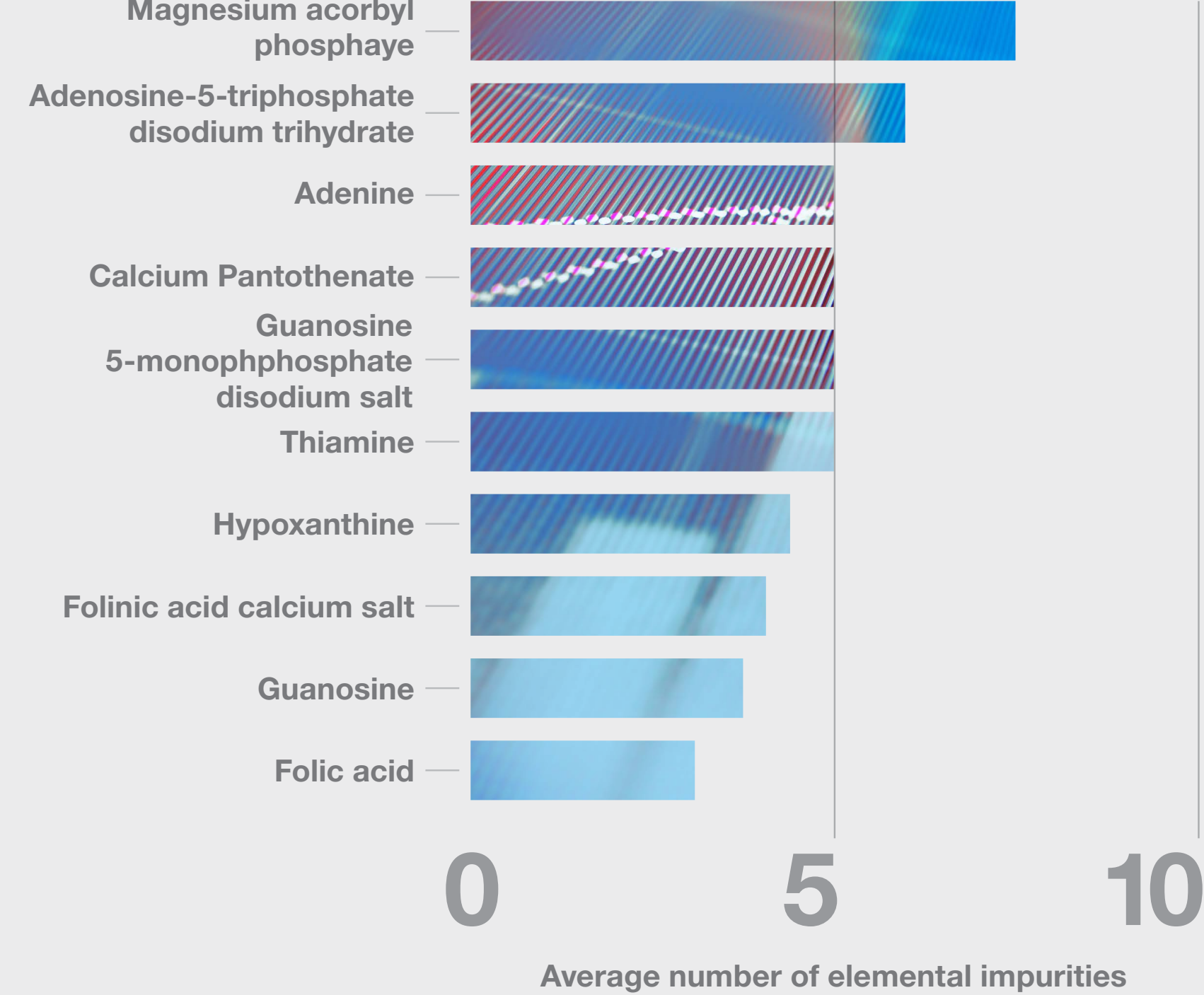
### Carbohydrates



### Amino Acids



### Vitamins and Nucleosides



## WHAT FACTORS CAN HELP ENSURE SUCCESSFUL RAW MATERIAL CHARACTERIZATION?

Having a thorough understanding of this data enables media manufacturers to understand where lot-to-lot variability is more likely to be introduced while maintaining vigilance of all raw materials in the supply chain.

01

### STATE-OF-THE-ART INSTRUMENTATION

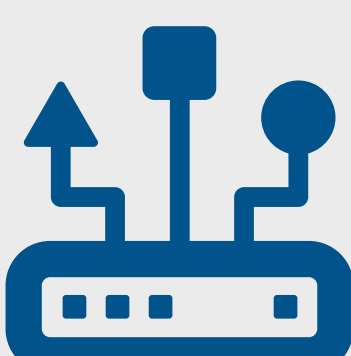
Investment in analytical equipment with high sensitivity can provide reassurance that even trace amounts of an impurity will be detected.



02

### DIGITAL INVENTORY SYSTEMS

Modern integrated inventory management systems can flag out of specification information so that quality teams can react quickly.



03

### OPEN COMMUNICATION AND DATA SHARING

A commitment to transparency with regard to characterization data can help media manufacturers increase confidence in the stringent analysis of raw materials at all bioproduction stages.

