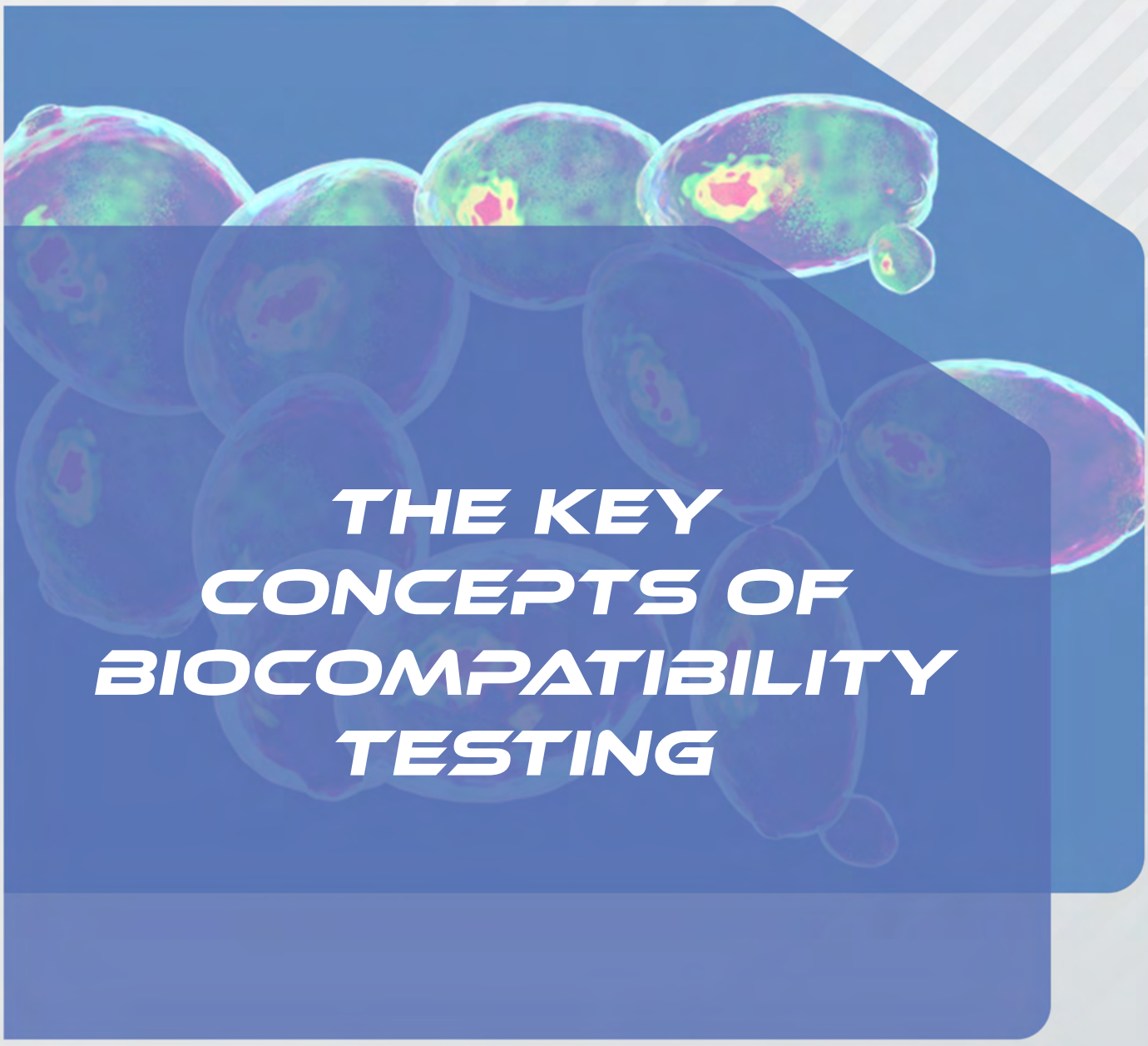
CMDC Labs

MAKING THE UNKNOWN KNOWN...



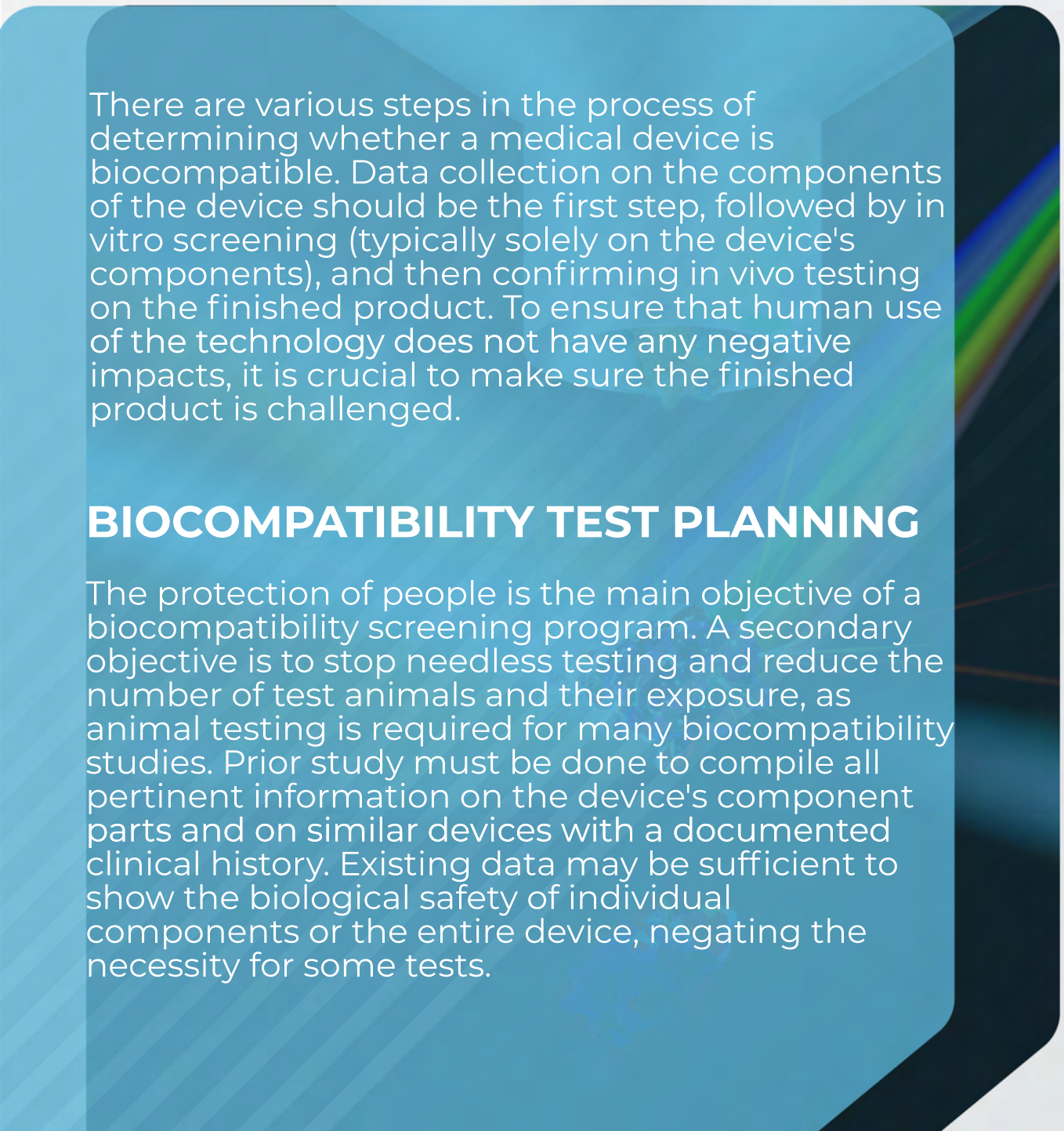
THE KEY CONCEPTS OF BIOCOMPATIBILITY TESTING

CMDC Labs, LLC I 105 S. Sunset St, STE O I Longmont I CO I 80501
info@CMDCLabs.com I +1 (720)-378-7387

PURPOSE OF BIOCOMPATIBILITY TESTING

By definition, biocompatibility is a measurement of how well-suited a device is to a biological system. Biocompatibility testing is done to verify if a device is fit for human usage and to see if there could be any possible adverse physiological impacts from using it. The International Organization of Standards has declared:

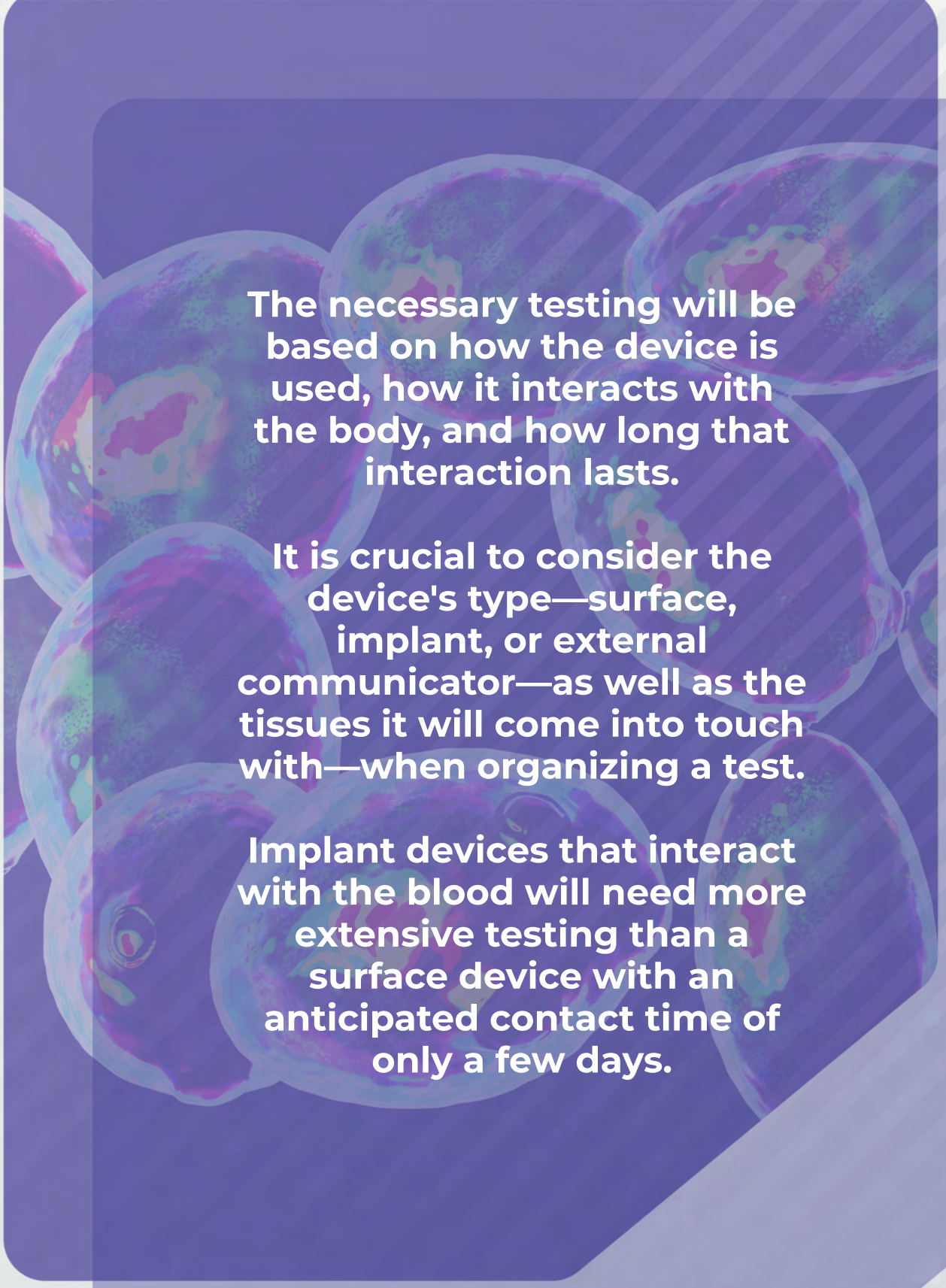
"The primary aim of this part of ISO 10993 is the protection of humans from potential biological risks arising from the use of medical devices." (ISO 10993-1:2009)



There are various steps in the process of determining whether a medical device is biocompatible. Data collection on the components of the device should be the first step, followed by in vitro screening (typically solely on the device's components), and then confirming in vivo testing on the finished product. To ensure that human use of the technology does not have any negative impacts, it is crucial to make sure the finished product is challenged.

BIOCOMPATIBILITY TEST PLANNING

The protection of people is the main objective of a biocompatibility screening program. A secondary objective is to stop needless testing and reduce the number of test animals and their exposure, as animal testing is required for many biocompatibility studies. Prior study must be done to compile all pertinent information on the device's component parts and on similar devices with a documented clinical history. Existing data may be sufficient to show the biological safety of individual components or the entire device, negating the necessity for some tests.



The necessary testing will be based on how the device is used, how it interacts with the body, and how long that interaction lasts.

It is crucial to consider the device's type—surface, implant, or external communicator—as well as the tissues it will come into touch with—when organizing a test.

Implant devices that interact with the blood will need more extensive testing than a surface device with an anticipated contact time of only a few days.

CONDUCTING TESTS

Typically, material characterization and analysis of the device's components are conducted prior to any biological testing. This entails removing leachable compounds from the device or device components and testing for hazardous chemicals or cytotoxicity.

Based on the device's intended usage, and in vitro evaluation can be performed prior to more complicated and costly in vivo biological testing. Some examples of in vitro tests may include skin irritation, hemocompatibility and immune response tests. Accurate and comprehensive in vitro evaluation is highly desirable as in vivo evaluation, depending on the type of testing required, may have a very long turnaround time.

EVALUATING THE DATA

After tests are completed and all data has been collected, it is recommended that a professional interpret the data and test results. This will show if additional testing is needed or if existing data is sufficient for a biological safety assessment of the device.

At CMDC Labs, We can handle all of your biocompatibility testing needs.