



Indianapolis – June 21, 2015
Body Art Sub-Committee
12:00pm – 2:00pm

Proposed Body Art Definitions and Standards

Association of Food and Drug Officials
*"Promoting Public Health, Fostering
Uniformity, and Establishing
Partnerships"*



Ken C. Stevenson
VP Regulatory Affairs
Ceutical Laboratories, Inc.
Dallas, Texas

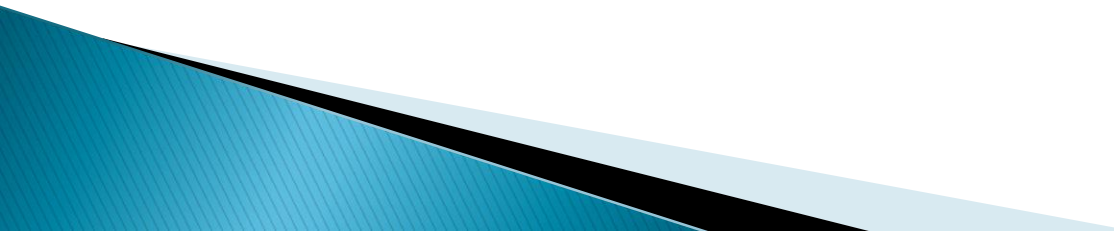


About the Speaker



- ▶ **Electronic submissions**
 - **Authoring: 2012 – present \approx 300 submissions**
 - **Consulting/training**
- ▶ **Management of data and regulatory information transmitted via the FDA Electronic Submissions Gateway (ESG), FURLS, CDER Direct and GUDID Web Interface**
- ▶ **Participation in electronic submissions implementation industry workgroups:**
 - **Devices**
 - **Drug Products**
 - **Facility/establishment registration**
 - **Invited by FDA to join the Regulated Clinical Research Information Management – Study Data Standards Project**
- ▶ **Body Art Sub-Committee**

Outline

- ▶ **History of Body Art**
 - ▶ **Current Population Statistics**
 - ▶ **Complications**
 - **Types**
 - **Causes**
 - ▶ **HACCP Introduction**
 - ▶ **HACCP Benefits**
 - ▶ **HACCP Proven Results**
 - ▶ **HACCP Proposal for the Body Art Industry**
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History of Body Art – Tattoos and Piercings

- ▶ Humans have tattooed our skin for thousands of years.
- ▶ Earliest known tattoos and piercings are from about 3,200 B.C.
- ▶ It is speculated that piercing is much older and predates recorded history.
- ▶ Tattoos and Piercings have served as:
 - Amulets
 - Status symbols
 - Declarations of love
 - Signs of religious beliefs
 - Adornments
 - Forms of punishment
 - Therapeutic

History of Body Art

Tattoos

- ▶ Otzi “The Iceman”
- ▶ September 1991
- ▶ Neolithic Period
- ▶ 3,500 – 2,300 B.C.
- ▶ 61 tattoos
- ▶ Therapy/acupuncture



History of Body Art

Tattoos



Siberian Ice maiden
Circa 5th century B.C.

History of Body Art

Tattoo

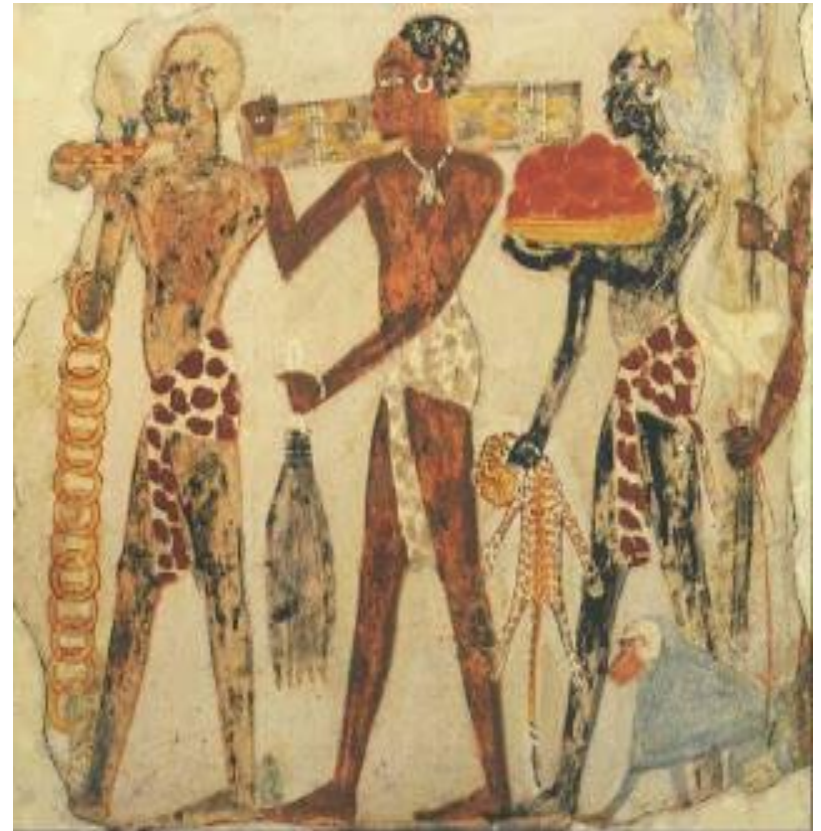


Chiribaya culture in coastal southern Peru flourished from around 900 – 1450 AD

History of Body Art

Piercings

- ▶ Ancient Egyptians
- ▶ Typically ear piercings
- ▶ Denotes
 - wealth
 - social status
 - religious beliefs



History of Body Art

Piercings

- ▶ Romans
- ▶ Circa 100 A.D.



History of Body Art

Piercings

- ▶ American Indians
- ▶ Wishram Tribe female
- ▶ Circa 1800 A.D.



U.S. Population Statistics

Tattoos

Tattoo Statistics	
Annual amount of U.S. spending on tattoos	\$1,650,500,000
Total percent of Americans (all ages) who have at least one tattoo	14 %
Percentage of U.S. adults 18 – 25 who have at least one tattoo	36 %
Percentage of U.S. adults 26 – 40 who have at least one tattoo	40 %
Total number of Americans that have at least one tattoo	45 million
Number of tattoo parlors in the U.S.	21,000

Statistics Brain Research Institute
Research Date: April 27, 2015
Compared to \approx 10 million in 1936

U.S. Population Statistics

Piercings

Body Piercing Statistics	Percent
Percent of Americans who have a body piercing other than ear lobe	14 %
Percent of pierced population that are women	72 %
Percent of Americans who have had their earlobes pierced	83 %

Statistics Brain Research Institute
Research Date: March 17, 2015

14% \approx 45,000,000 people

72% \approx 33,000,000 woman

83% \approx 274,000,000 people with earlobes pierced

U.S. Population Statistics

Reported Complications

Tattoos

- ▶ A study conducted at NYU Medical Center revealed that six percent of New Yorkers with a tattoo have experienced long-term medical complications related to their ink, including tattoo-related rash, severe itching, or swelling.

The American Association for the
Advancement of Science



U.S. Population Statistics

Reported Complications

Tattoos

- ▶ **Ten percent of respondents to the study experienced some type of short-term complication, such as delayed healing, pain, swelling, and infection, within weeks of getting their tattoo.**

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U.S. Population Statistics

Reported Complications Tattoos

- ▶ **Almost half (44 percent) of chronic reactions were to red ink, even though only slightly more than a third (36 percent) had tattoos with red ink. One-third of chronic cases involved black ink, while over 90 percent of tattoos encompass black coloring.**

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U.S. Population Statistics

Reported Complications

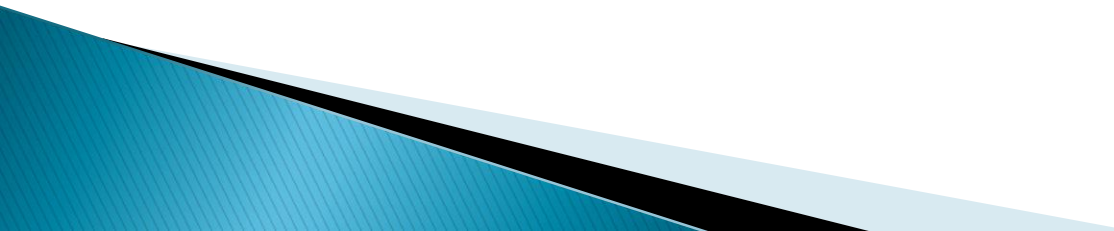
Piercings

Piercing Complication Statistics	
Percent of piercing's that had complications	31 %
Percent of piercing's where professional help was needed	15.2 %
Percent of piercing's that required hospitalization	0.9 %

Statistics Brain Research Institute
Research Date: March 17, 2015

Types of Complications

Tattoos and Piercings

- ▶ **Allergic Reaction**
 - ▶ **Granulomas**
 - ▶ **Keloid Formation**
 - ▶ **Cancer**
 - ▶ **MRI Complications**
 - ▶ **Infections (Staph, hepatitis, etc.)**
 - ▶ **Removal Problems**
 - ▶ **Heavy Metal Poisoning**
- 

Allergic Reactions

Tattoos and Piercings



- ▶ Allergies to metals are common.
- ▶ Allergic reaction to one of the metals or alloys used in the inks or piercing.
- ▶ Cases have occurred with nickel, gold and platinum from ear piercings.

Granulomas

Tattoos and Piercings



- ▶ **Nodules that may form around material that the body perceives as foreign, such as:**
 - particles of tattoo pigment
 - piercings

Keloid Formation

Tattoos and Piercings



- ▶ Scars that grow beyond normal boundaries.

Infections

Tattoos and Piercings



- ▶ **Unsterile equipment, re-use ink**
- ▶ **Poor sterility practices**
- ▶ **Poor quality body art materials**

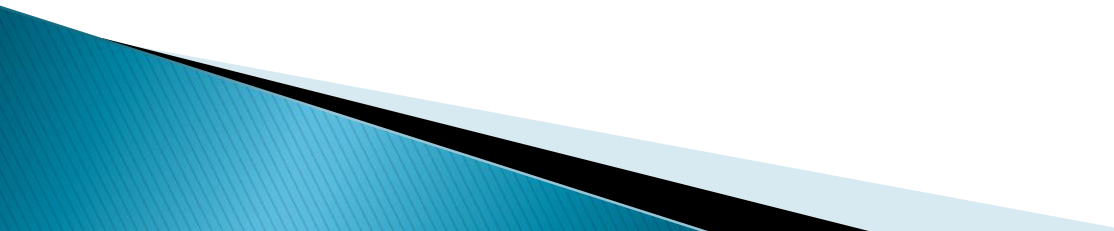
Causes of Complications

Tattoos

- ▶ **Many of today's tattoo inks contain:**
 - metallic salts (oxides, sulphides, selenides)
 - organic dyes
 - plastics suspended in a carrier solution
- ▶ **European Commission reports:**
 - close to 40% of organic colorants used in permanent tattoo inks in Europe are not even approved for use on the skin as a cosmetic ingredient.
 - Just under 20% of the colorants studied contained a carcinogenic aromatic amine.
- ▶ **Many of the chemicals found are intended for use in writing and printer inks, as well as automobile paints.**

Causes of Complications

Tattoos

- ▶ The FDA does not require ingredient disclosure on the inks
 - ▶ They are considered proprietary (trade secrets).
 - ▶ Tattoo inks may contain any chemical, including chemicals that are:
 - mutagenic (capable of causing mutations)
 - teratogenic (capable of causing birth defects)
 - carcinogenic (capable of causing cancer)
 - involved in other biochemical reactions in the body that might take decades to appear
- 

Causes of Complications

Tattoos

- ▶ **The carrier solution might contain harmful substances such as:**
 - denatured alcohols
 - Methanol
 - rubbing alcohol
 - Antifreeze
 - Detergents
 - formaldehyde and other highly toxic aldehydes



Causes of Complications

Tattoos

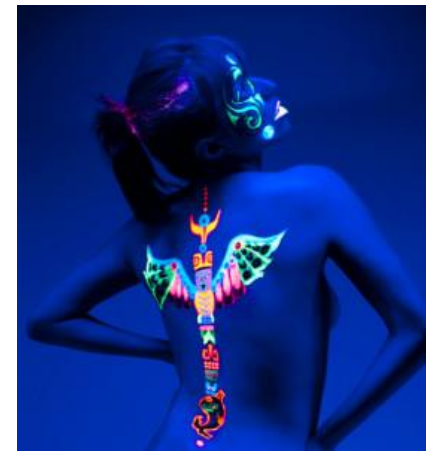
- ▶ A wide range of dyes and pigments are now used in tattoos including:
 - inorganic titanium dioxide and iron oxides
 - carbon black
 - azo dyes
 - Acridine
 - Quinoline
 - Phthalocyanine
 - naphthol derivatives
 - dyes made from ash
 - other mixtures
 - Acrylonitrile butadiene styrene (ABS plastic) has been used in some pigmented brands.



Causes of Complications

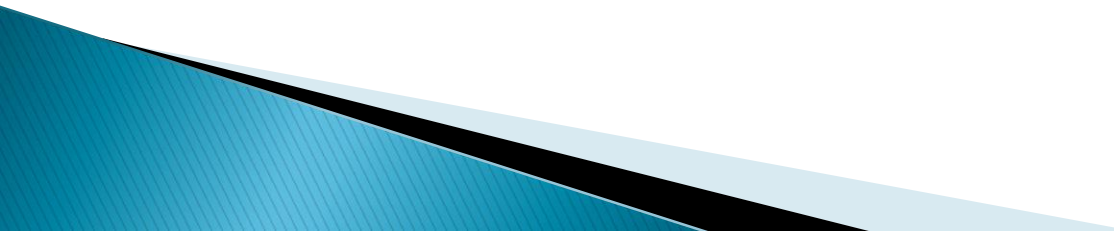
Tattoos

- ▶ Allergic reactions have occurred with some of the many metals put into tattoo inks:
 - Nickel, one of the most common metal allergies
 - mercury in red
 - cobalt blue
 - cadmium sulfite in yellow
- ▶ Some inks have high levels of lead, some contain lithium, and blue inks can contain copper.
- ▶ Some new “glow in the dark” inks can be radioactive.




Causes of Complications

Tattoos

- ▶ When alcohol is used as part of the carrier base in tattoo ink or to disinfect the skin before application of the tattoo, it increases the skin's permeability, helping to transport more chemicals into the bloodstream.
 - ▶ Alcohol also works synergistically with mutagens, teratogens, and carcinogens to make them even more harmful, increasing the chance that they may cause mutation or disease, both at the site of the tattoo and systemically.
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Causes of Complications

Tattoos

- ▶ The use of needles in tattoo application, poor technique, and contaminants in the tattooing environment all present the risk of contracting infectious diseases.
 - ▶ White & Blue Lion, Inc. recalled due to pathogenic bacterial contamination:
 - tattoo inks
 - tattoo needles
 - tubes
 - ink cups
 - kits
- 



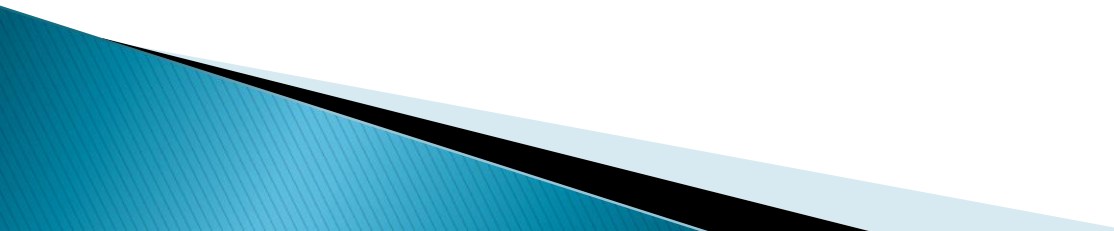
Causes of Complications

Piercings

- ▶ **Most body piercing jewelry is made of:**
 - stainless steel
 - Gold
 - Niobium
 - Titanium
 - alloys
- ▶ **Surgical stainless steel rarely causes allergic skin reactions; however, not all stainless steel products are nickel-free.**

Causes of Complications

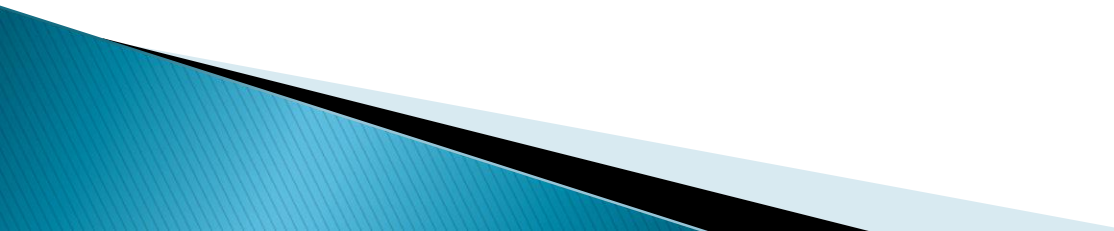
Piercings

- ▶ **Other features to consider in body piercing jewelry include:**
 - **ease of removal (in case of trauma or radiographs)**
 - **surface smoothness**
 - **capacity to with-stand autoclaving and cleaning**
 - **painted jewelry**
 - **no glue**
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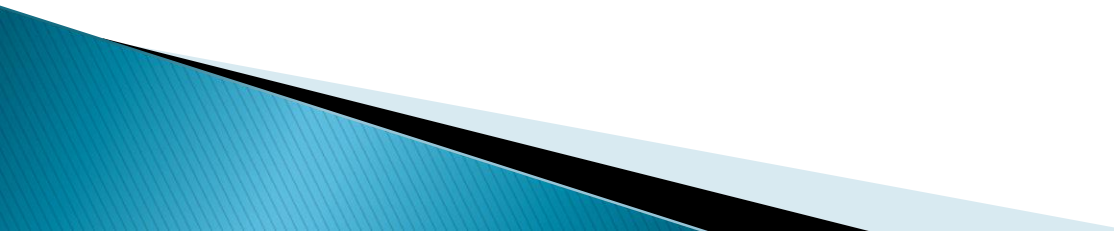
HACCP Introduction

- ▶ Hazard Analysis and Critical Control Points
- ▶ HACCP is a management system addressing product safety.
- ▶ Analysis and control hazards/contaminants:
 - biological
 - chemical
 - physical
- ▶ 7 HACCP principles are implemented:
 - raw material production, procurement and handling
 - manufacturing
 - distribution
 - use/consumption

HACCP Seven Principles

- ▶ Principle 1: Conduct a hazard analysis.
 - ▶ Principle 2: Determine the critical control points (CCPs).
 - ▶ Principle 3: Establish critical limits.
 - ▶ Principle 4: Establish monitoring procedures.
 - ▶ Principle 5: Establish corrective actions.
 - ▶ Principle 6: Establish verification procedures.
 - ▶ Principle 7: Establish record-keeping and documentation procedures.
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HACCP Benefits

- ▶ Saves business money in the long run
 - ▶ Helps protect final consumer
 - ▶ Product safety standards increase
 - ▶ Product quality standards increase
 - ▶ Organizes processes to produce safe products
 - ▶ Organizes staff promoting teamwork and efficiency
 - ▶ Least burdensome approach
 - ▶ Cost effective
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HACCP Success

Food Industry

- ▶ **HACCP Inspection Models Project (HIMP)**
- ▶ **Marked improvement in HIMP food manufacturing facilities**
- ▶ **Reduction of contaminated products to the rate of 0.000004% or 4 per 100 million units in HIMP establishments**
- ▶ **Average of about 1.5 times lower than non-HIMP establishments**

**Evaluation of HACCP Inspection
Models Project (HIMP)
United States Department of Agriculture
Food Safety and Inspection Service**

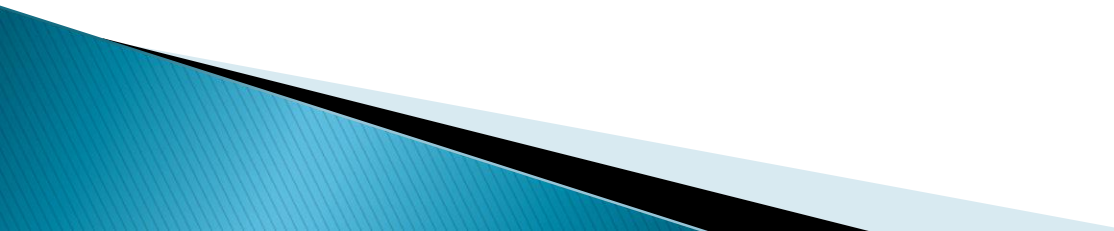
HACCP

Proposed Standards and Guidelines

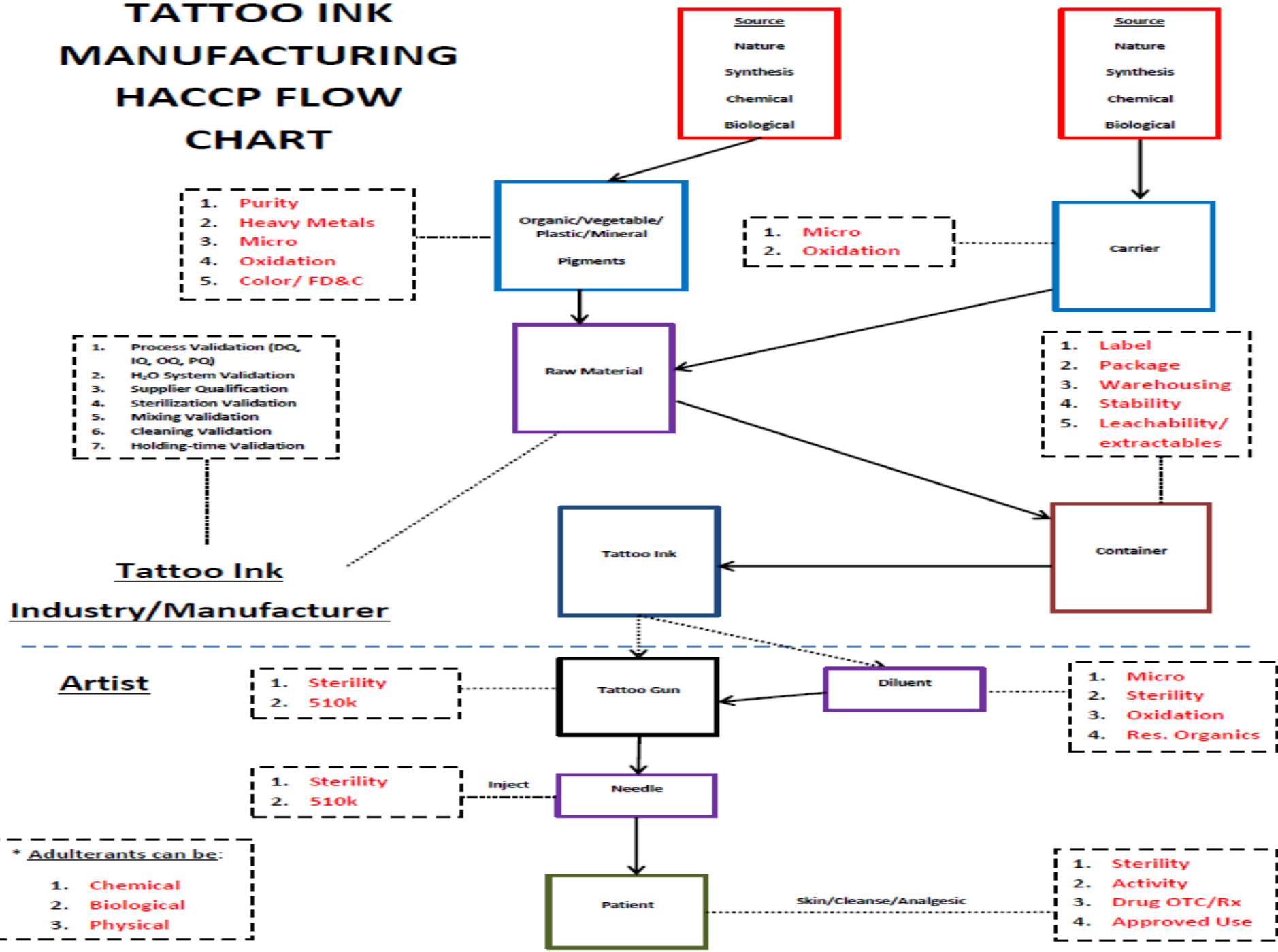
- ▶ **Manufacturers would evaluate, control and monitor:**
 - product ingredients
 - processing procedures
 - packaging
 - storage
 - intended use
 - facility and equipment function and design
 - plant sanitation including employee hygiene
- ▶ **Determine the potential effect of each on the safety of the finished body art material for the intended consumer.**

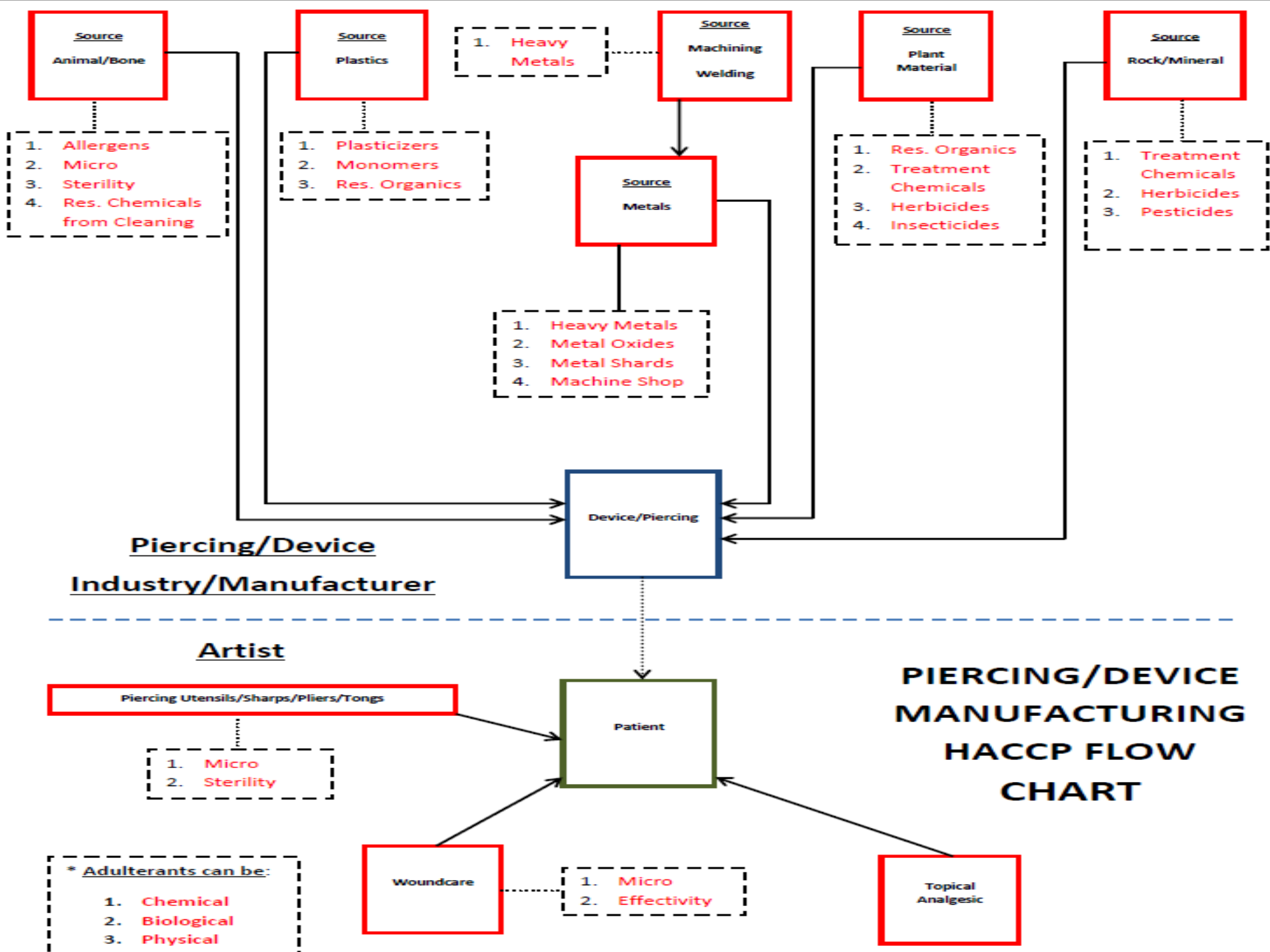
HACCP

Proposed Standards and Guidelines

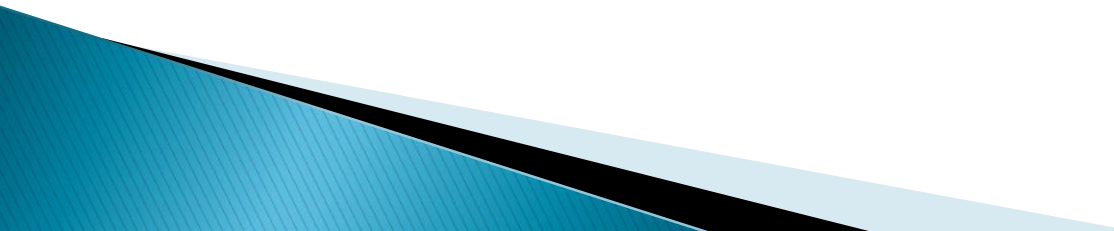
- ▶ **Microbiological contamination**
 - ▶ **Parasites**
 - ▶ **Chemical contamination**
 - ▶ **Unlawful pesticides residues**
 - ▶ **Decomposition in a body art material**
 - ▶ **Natural toxins, including endotoxins**
 - ▶ **Unapproved use of body art material or color additives**
 - ▶ **Presence of undeclared ingredients**
 - Allergens
 - Others
 - ▶ **Physical hazards**
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TATTOO INK MANUFACTURING HACCP FLOW CHART

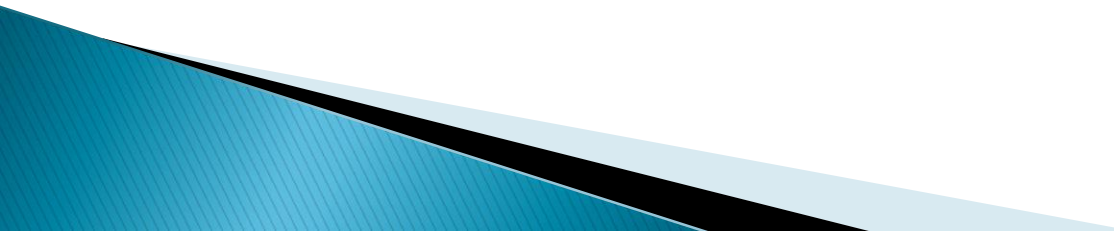




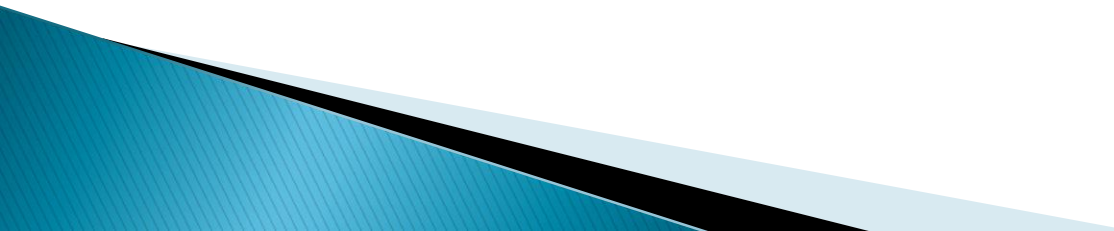
HACCP Implementation Challenges

- ▶ **Industry buy-in**
 - ▶ **Cost**
 - Most of enterprises are small and medium-sized with limited resources (money, manpower,..)
 - ▶ **Lack of knowledge, training (in initial stage especially)**
 - ▶ **Have to upgrade the factory conditions, equipment; regular maintenance**
 - ▶ **Difficulties in management of raw material's origin**
- 

HACCP Implementation Challenges

- ▶ **Psychology (fear of liability)**
 - ▶ **Conflicting objectives in quality management and business unit**
 - ▶ **Regulations and standards of other countries**
 - ▶ **Cooperation and signed international agreements with the competent authorities of the importing countries**
- 

Possible Additional Solutions

- ▶ National database for reporting of adverse events
 - ▶ National database for raw material suppliers
 - ▶ Manufacturing facility registration
 - ▶ U.S. Agent registration
 - ▶ Distributing facilities database
 - ▶ Electronic product listings
 - ▶ Others?
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Thank You

- ▶ Association of Food and Drug Officials
- ▶ Association of Professional Piercers
- ▶ Alliance of Professional Tattooists
- ▶ National Tattoo Association



DISCUSSION