



129th AFDO Annual Educational Conference



Dallas,
Texas

2025 Body Art Committee Educational Track

Amy Ward
A-ok Tattoo
Roswell, New Mexico

Ken C. Stevenson
CeutiReg LLC and Ceutical Laboratories Inc.
Flower Mound, Texas

**Supplier Agreements and Quality
Agreements –
Practical Agreements for the Tattoo and
PMU Industries**



Ceuti Reg

CGMP COMPLIANCE SPECIALISTS

Part 1 - Supplier Agreements and Quality Agreements –
Practical Agreements for the Tattoo and PMU Industries

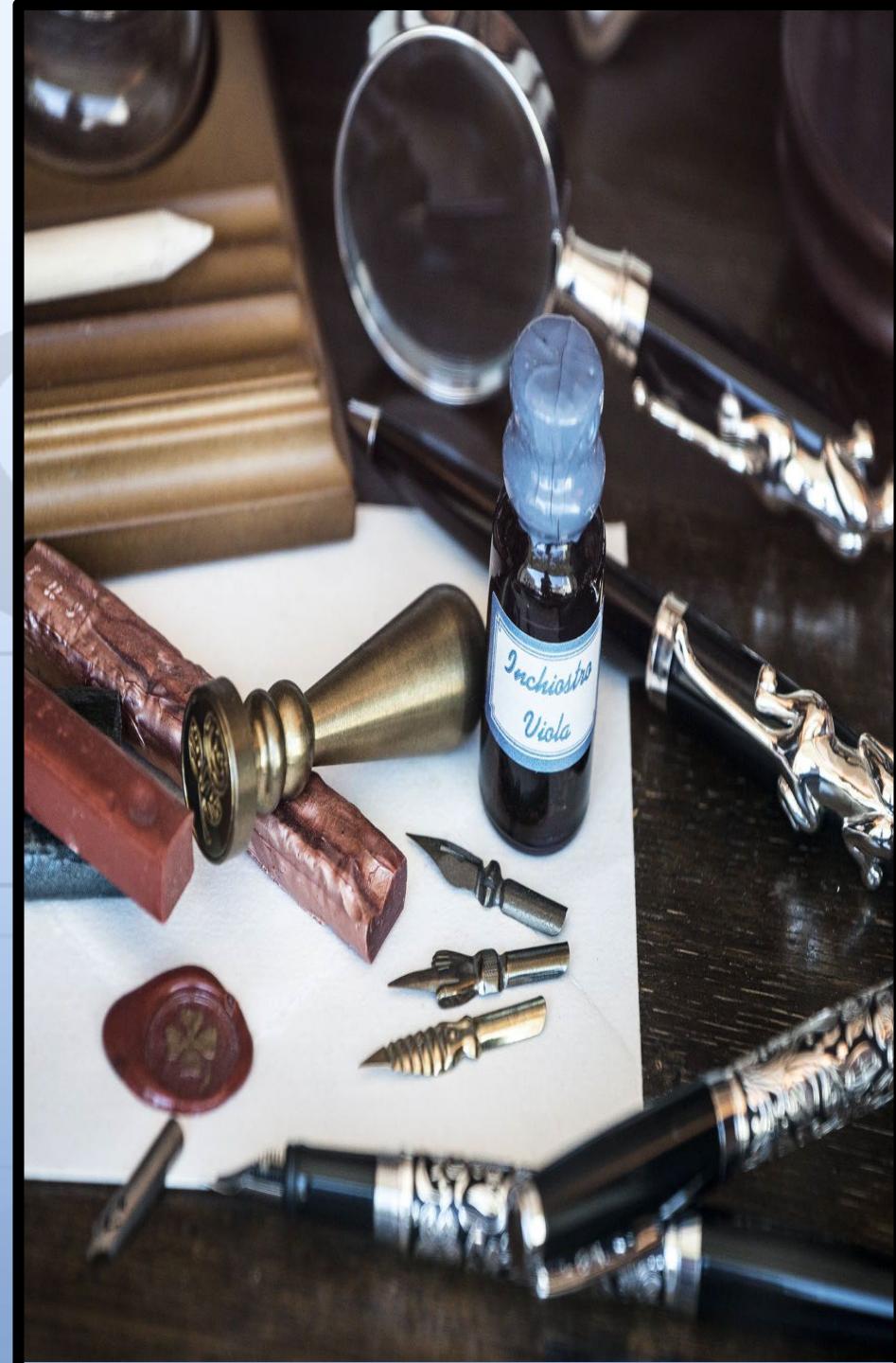
Ken C. Stevenson

President

CeutiReg, LLC
Ceutical Labs

Agenda for Part 1 of the Discussion

- The Seven Elements of MoCRA
- Overview of Supplier and Quality Agreements
- Similarities
- Differences
- Manage Supplier Transactions
- Best Practices



MoCRA – 7 Elements of Compliance

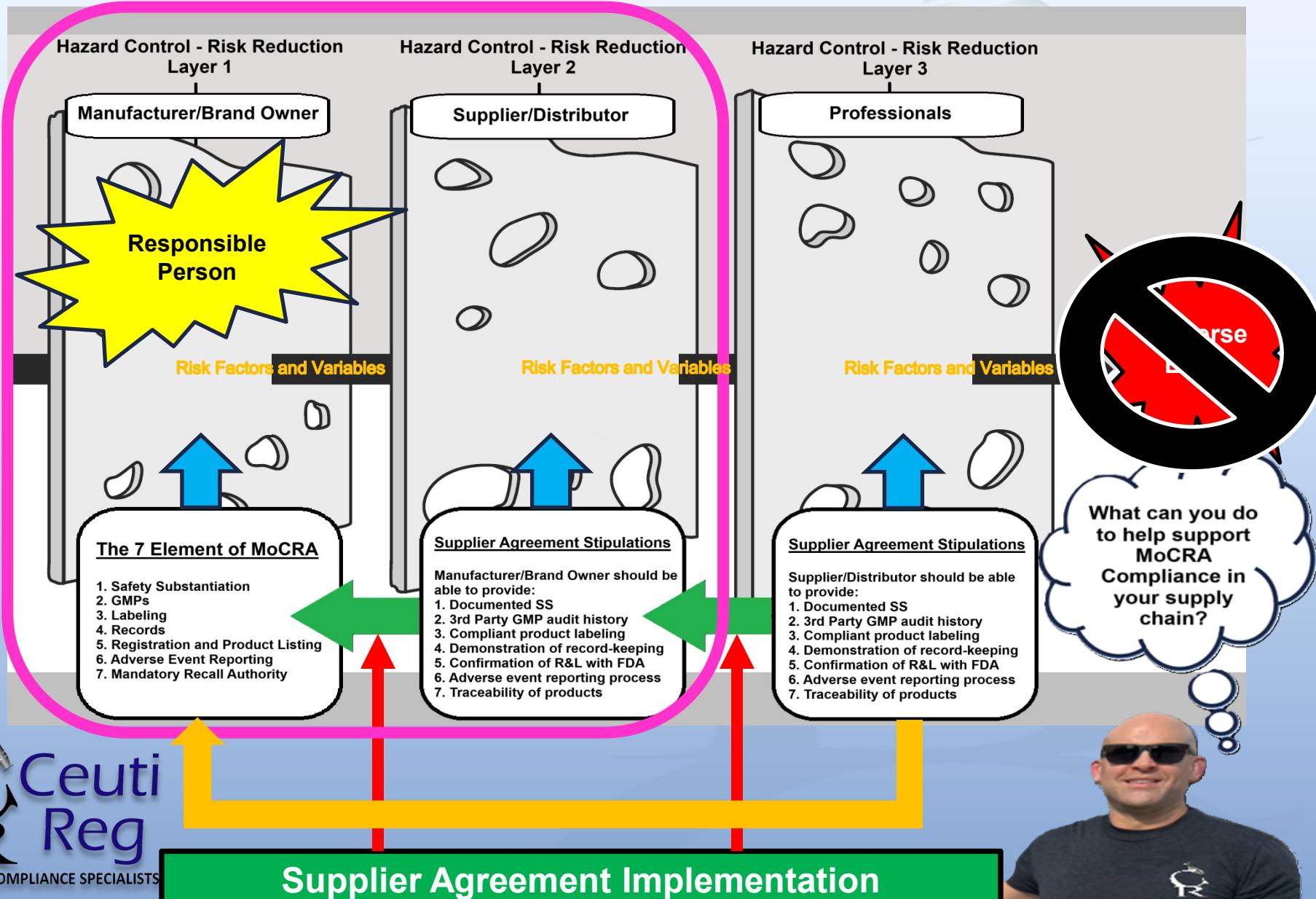
The Modernization of Cosmetic Regulation Act of 2022

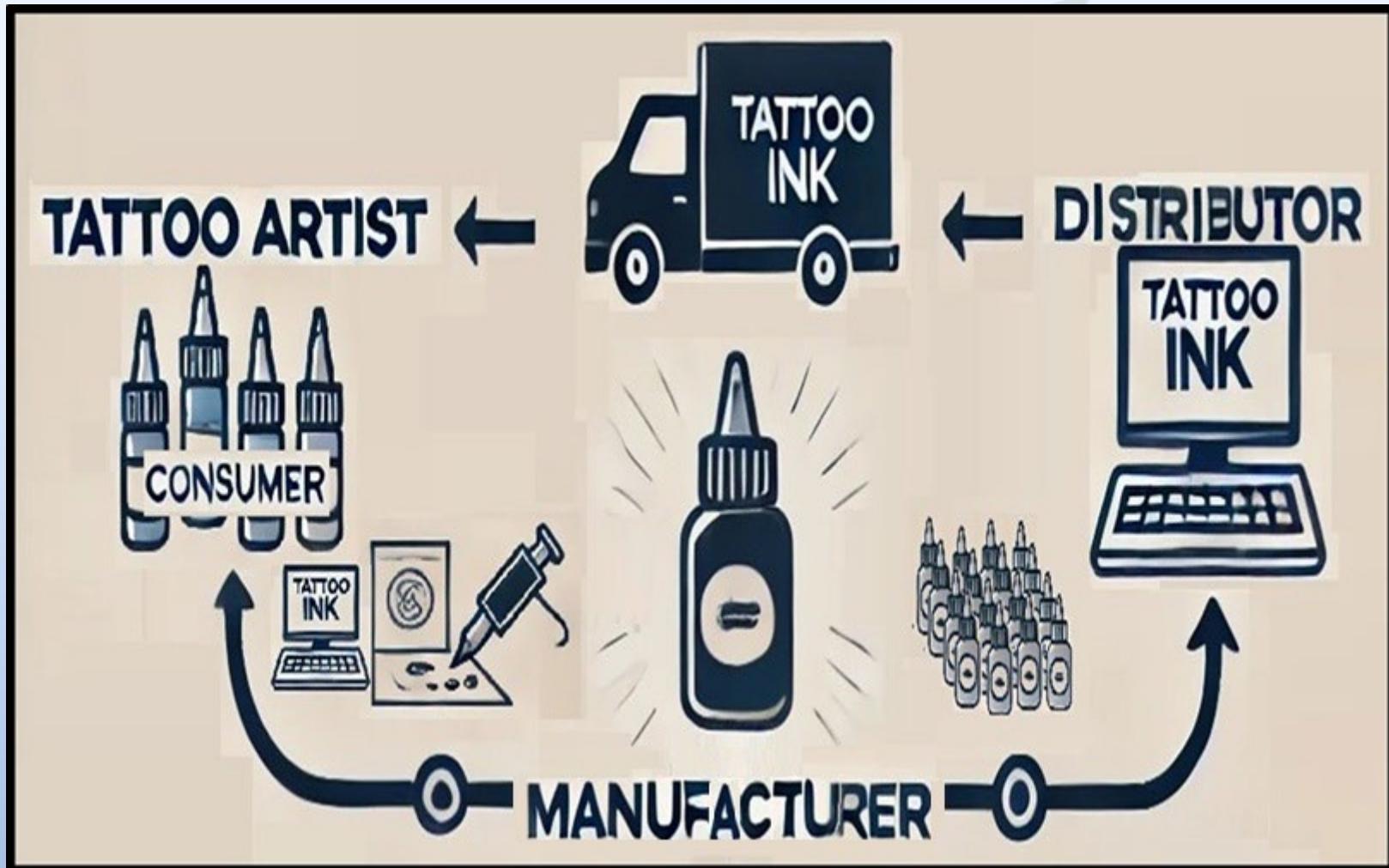
1. Safety Substantiation
2. GMPs
3. Labeling
4. Records
5. Registration and Product Listing
6. Serious Adverse Event Reporting
7. Mandatory Recall Authority



Tattoo Ink and Permanent Make-Up

Swiss Cheese Model of Adverse Event Mitigation





Overview of Supplier and Quality Agreements

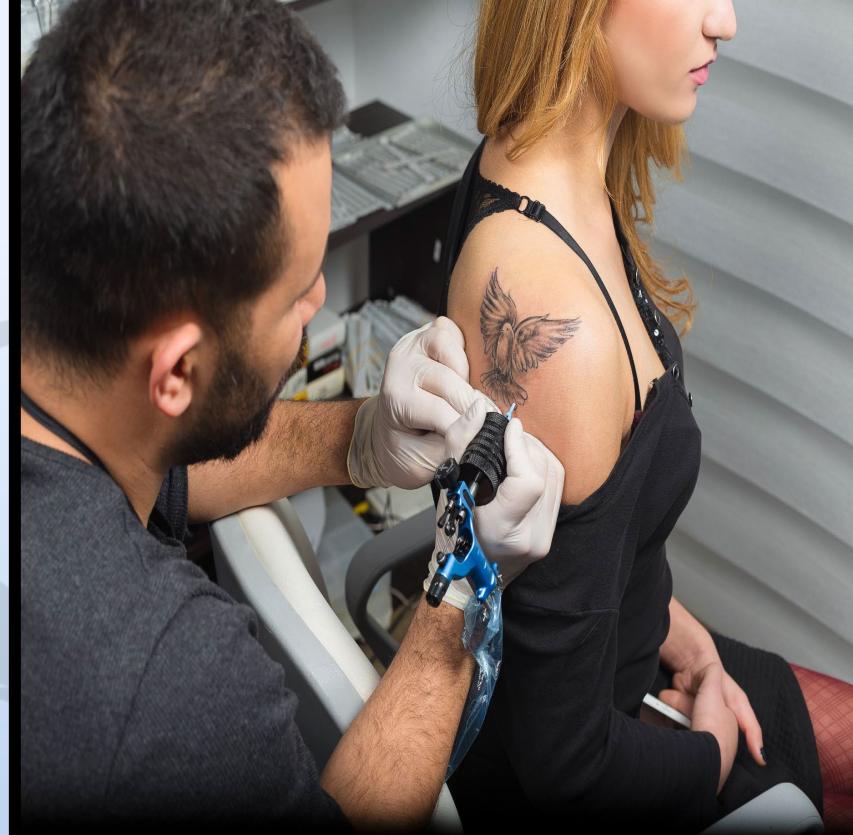
Introduction

- Supplier Agreements and Quality Agreements are both **critical in supplier management.**
- They serve different purposes but share some similarities.



Similarities in Supplier and Quality Agreements

- Formalize Relationship
- Legally Binding
- Clear Expectations
- Clarify Terms



Similarities in Supplier Agreements and Quality Agreements

Formalize Relationship

Both establish formal agreements between you and your supplier.

Legally Binding

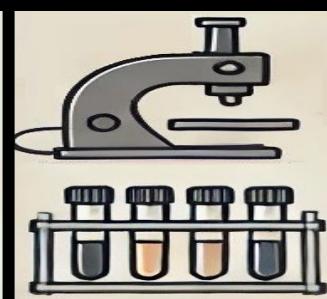
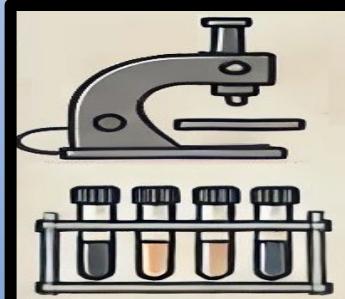
Both are legally enforceable documents.

Clear Expectations

Both define roles, responsibilities, and performance metrics.

Clarify Terms

Both help clarify terms to avoid confusion, prevent misunderstandings and ensure compliance.





Differences Between Supplier and Quality Agreements

- Focus
- General Provisions
- Purpose



Differences Supplier Agreements Vs. Quality Agreements

Focus

Broad business terms and conditions.

Quality standards and product integrity.

General Provisions

Pricing, delivery schedules, payment terms, confidentiality, liability, intellectual property.

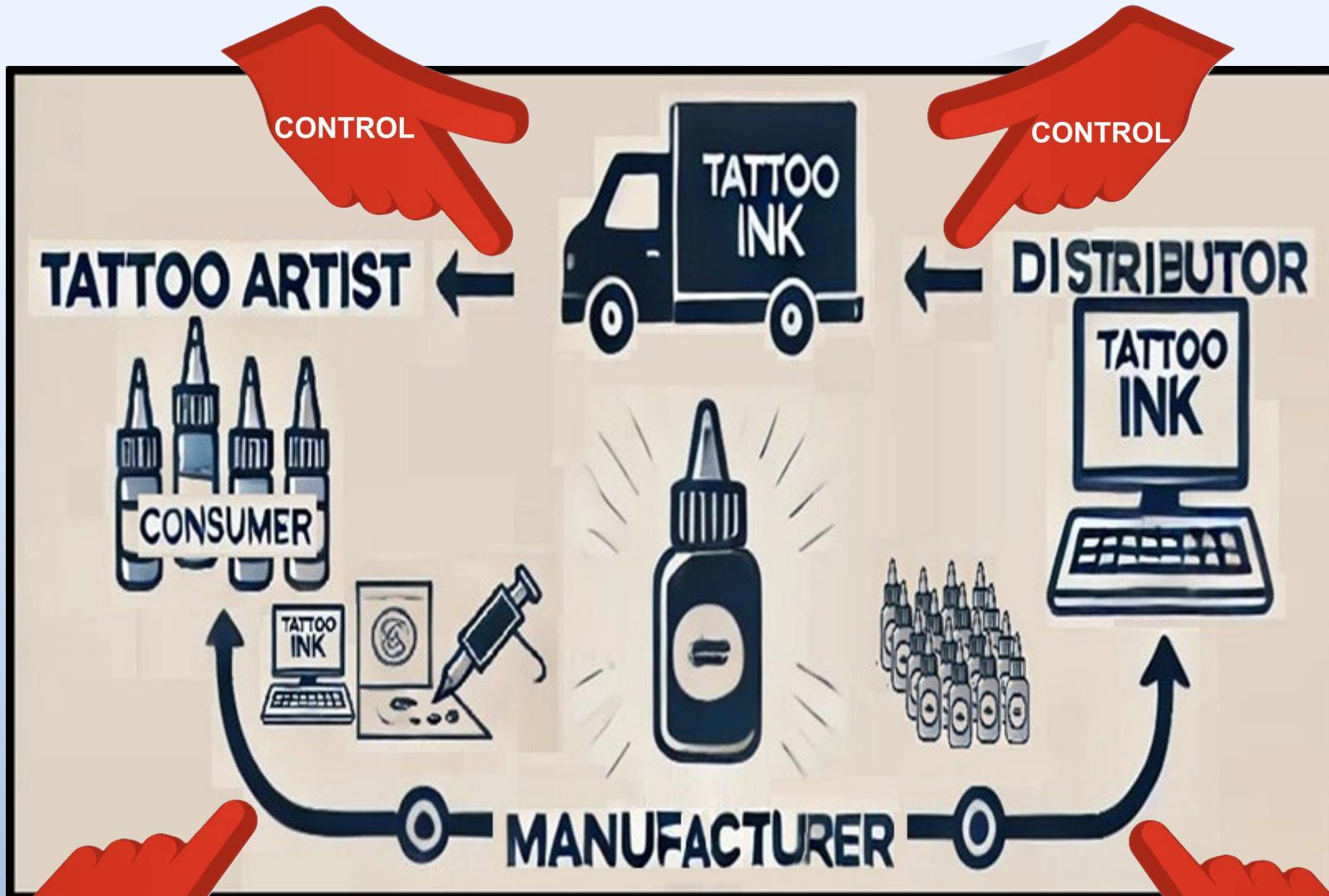
Product specifications, testing procedures, quality control, non-conformance handling, auditing.

Purpose

Defines the general business relationship and ensures smooth transactions.

Ensures compliance with quality, safety, and regulatory requirements, consistency across batches/shipments.

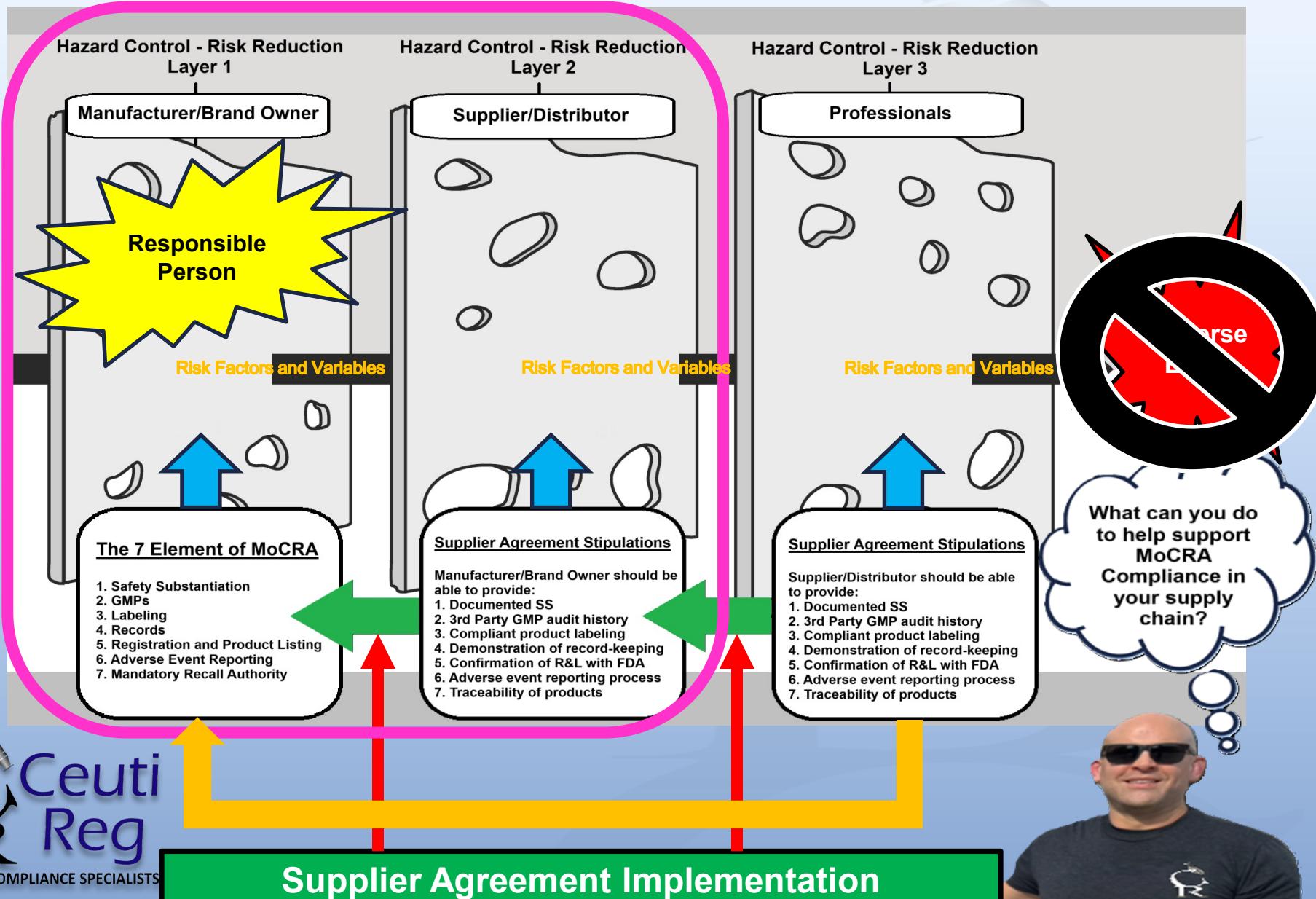




CGMP
Reg

Tattoo Ink and Permanent Make-Up

Swiss Cheese Model of Adverse Event Mitigation



TATTOO ARTISTS SUPPLY CHAIN



Avoid a Supply Chain Train Wreck

Positive Impacts

- Ability to market products as “safe.”
- Enhanced consumer trust in tattoo and PMU services.
- Could provide professionals with peace of mind about what they are using/applying to a client’s body.
- Serious adverse event reporting may enhance the safety of tattoo inks and help to prevent outbreaks.
- Cosmetics went from being the least regulated to one of the most regulated segments under FDA’s regulatory responsibility.
- Choosing suppliers is now a much more predictable process.
- Now professionals won’t have to rely on the supplier’s “word” for assurance of safety.
- Compliance with MoCRA may help stabilize the supply chain.
- Bad products may be removed from the supply chain quicker.

Part 2 - Supplier Agreements and Quality Agreements – Practical Agreements for the Tattoo and PMU Industries

Ink Quality & Safety Control : The #1 way we can ALL be Professional, Ethical tattoo artists

**Amy Ward
A-ok Tattoo Studio
Shop Owner and
Professional Tattoo Artist
Roswell, New Mexico**



Intro: Amy Ward

Personal Background: Professional Tattoo Artist



A-ok Tattoo Shop

- Body Art Establishment owner of A-ok TATTOO est. 2000
- Apprentice Sponsor: approved by NM to train
- Guest Artist
- Since beginning my career in 1999, tattooing has grown in popularity as a collected art form.



Intro: Amy Ward

Personal Background: Fine Artist



- Studied Fine Art 3D background:

- Education in pigments : paint, ceramic glaze
- I'm inspired by the Art form of Tattooing :
 - 2D art form on a 3D canvas
 - Living 3D canvas : Protect Health/ life of client
 - Ink is all that's left in skin : 3 components to Ink Longevity
 - Is it archival/ lasting as long as possible on given canvas?
 - Body Art : a gallery on display everywhere, all the time, personal interaction



Intro: Amy Ward

Personal Background: Safe Tattooing

- **Safe Tattooing:** Goals for me and my client = Professional ink Standard
 - Tattoo artist is a crucial checkpoint for ink between the manufacturer and client.
- **Passion:** What drives me to understand what ink I am applying to client?
- **Ethical:** know what risks/ if any could affect client - collecting/ buying/ living with ink permanently.



Intro: Amy Ward

Personal Background: Safe Tattooing

- **Advocate:** for transparency about the process and products I will use in the Tattoo procedure as a trusted Professional. Tattoo Collector's Rights
- **Shop Policy** for informed consent: collecting/ buying/ living with Tattoo permanently.
- **Collector:** Who I collect body art from ***and their Ink standards*** can affect me for the rest of my life.
 - How can I navigate getting tattooed while minimizing Risk?





Tattoos on the body of Ötzi, the Tyrolean Iceman. (Photograph © South Tyrol Museum of Archaeology/EURAC/Samadelli/Staschitz)

<https://www.si.edu/stories/ancient-ink-iceman-otzi-has-worlds-oldest-tattoos>



Tattoo & Permanent Makeup Collection

Why should anybody care about ink composition?

- **Sources of Tattoo Ink:** Traditionally - pigment mixing part of Craft // Modern - manufactured
- **Tattoo / PMU Statistics:** *See References at End
 - People collect Body Art for many reasons:
 - Historically (ice man) : Groups/ individuals collected images to show their journey, status, health benefits, decorative, aesthetic, cosmetic.
 - Increase in Collection:
 - How many ppl have tattoos? Americans: 35% 2021, 40% 2024 (of adults age 25-40) 24% of all adults
 - Global Economic Growth: 2024= USD\$ 2.22 Billion
 - Tattoo Industry and is expected to nearly double its global market size from \$1.75 billion in 2021 to \$3.55 billion by 2029.
 - Global Tattoo ink market = projected \$550 million by 2026 - demand increase
 - 2024 United States have more than 26,111 tattoo parlors
 - Tattoo Conventions worldwide = 500-2000 events annually, attracting 1 million visitors combined
 - Use of vegan/ cruelty free inks has increased 25% (2019-2022)



Tattoo & Permanent Makeup Collection

Why should anybody care about ink composition?

- U.S. Adverse Event Reports / Recalls- recent history 2003-2021: 15 recalls (13 manufacturers - 200 ink products) Micro, Allergy, label ingredient transparency -Sealed bottles : manufacturing process
 - Good info: Kathleen Lewis: AFDO Lecture
 - Statistics relatively short-term:
 - Medwatch FDA: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>
- Growth in Tattooing popularity - may lead to more opportunities for Adverse Events
- Current common Myths: Let's seek the Truth
 - Body Art Product Regulation is not helpful
 - Ink is never harmful
 - Tattoo Artist : No responsibility for the ink we apply
 - The manufacturer is doing what they are required to do. I can take their word for it.
 - I will always be able to get a current supply of Ink from that supplier



How do I Buy quality / safe inks consistently?

Keys to help implement Ink Supplier relationship:

- Supplier Quality Control is NOT a new Concept: Required in Food, Cosmetics, Dietary Supplements, Drugs
- What does this look like in my shop: Supplier Agreements: Requirements for Ink Suppliers ?
 - Practitioner Responsibility: I use Ink products that have regulations and could present risk :
 - Ink manufacturer verifies safety product : SS, good GMPs/ acceptance criteria: Documentation that they have satisfied the 7 elements of MoCRA
 - In the event of a Recall it is not the only the ink provider who is responsible, it is everyone in the supply chain
 - Professional Licensure: requirements , not adulterated, lot #,

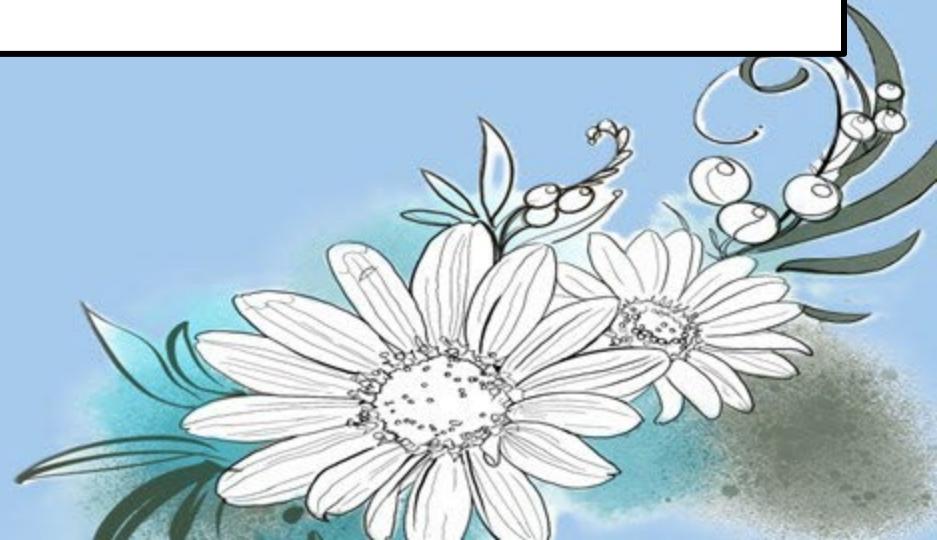


New Mexico Tattoo Artist Licensure Ink Requirements

H. All inks, dyes, pigments and sharps shall be specifically manufactured for performing body art procedures and shall not be adulterated. Immediately before applying a tattoo, the quantity of the dye to be used for the tattoo shall be transferred from the bottle and placed into sterile, single use paper cups or plastic caps. Upon completion of the tattoo, these single cups or caps and their contents shall be discarded.

I. For body piercing and tattooing establishments primarily utilizing a Statim autoclave, reusable items shall be sterilized in an autoclave in a bulk load without sterilization pouches, previous to sterilization in the Statim autoclave, for the body piercing or tattoo procedure. Reusable instruments and single use items sterilized in a Statim autoclave cassette must be used immediately after opening the Statim autoclave cassette. The items contained in the Statim autoclave cassette shall be used for one client only and shall include use of an integrator strip.

[16.36.5.9 NMAC - Rp, 16.36.5.9 NMAC, 02/04/2016]



How can I Buy quality / safe inks consistently?

Keys to help implement Ink Supplier relationship:

- **Safe ink:** (Resource: [FDA.gov](https://www.fda.gov) — article “Tattoos & Permanent Makeup: FACT SHEET”)
 - Safe: indicates likelihood of harm is reduced to an ACCEPTABLE level
 - Risk Assessment: Process of identifying and analyzing hazards and associated risks
 - Adverse event Protocol: Client Records need to be kept
 - FDA Medwatch reporting program: Serious events must be reported
- **Past known Ink Issues:**
 - Labeling: ingredients are not present when listed/are present when not listed/sterility claims
 - MoCRA: FDA requires Allergen on label
 - Micro contamination: Management includes implementation of measures to control/eliminate Identified Risks:
 - Engineering controls, Administrative controls, PPE



How can I Buy quality / safe inks consistently?

Keys to help implement Ink Supplier relationship:

- **How does contamination occur?**
 - GMPs are not always perfectly executed -ex: human error
 - Ink can pass all testing & how it is handled/ stored/ packaged is **sometimes** the source of contamination.
 - Practitioner needs to understand how to store ink and read label: ex. Traceability, allergens, expiration.
 - Traceability is needed if Adverse Event occurs: Prevent exposure to contaminated Ink Lot #
- **Ink Supplier Agreement:**
 1. Quality & Compliance Documentation Request
 2. Supplier Agreement
 3. Quality Agreement
 4. *Consultant can assist with Supplier Agreements



Sample Document Request

[Your Name/Business Name]

[Your Address]

[City, State, ZIP Code]

[Your Email]

[Your Phone Number]

[Date]

[Manufacturer's Name]

[Manufacturer's Address]

[City, State, ZIP Code]

Subject: Request for FDA Compliance Documentation for Tattoo Ink Products

Dear [Manufacturer's Name or Compliance Officer],

I am writing to formally request documentation verifying that your tattoo ink products comply with all applicable U.S. Food and Drug Administration (FDA) regulations and safety standards. As a [tattoo artist/tattoo supply distributor/tattoo retailer], it is essential for us to ensure that the products we [use/distribute] meet the highest safety and quality standards.

To confirm compliance, we kindly request the following:

1. Certificate of Compliance – A document stating that your inks adhere to FDA/MoCRA stipulations including but not limited to:
 - a. Documented **Batch Specific Safety Substantiation.** (? C of A)
 - b. Documented **3rd party audit results** or attestation of implementation of Good Manufacturing Practices (GMP) at your manufacturing facility
 - c. **Confirmation that your labeling meets FDA guidelines**, including ingredient disclosure and safety warnings.
 - d. **Third-Party Laboratory Test Results/ Records** - Recent test reports confirming the absence of harmful contaminants, such as heavy metals, bacteria, or other unsafe substances.
 - e. Documentation or attestation that the **products** being purchased by [tattoo artist/tattoo supply distributor/tattoo retailer] are manufactured in an FDA registered facility and **have been listed with the FDA**.
 - f. Instructions for the process that should be used and who to contact about adverse events related to the use of these products.
 - g. Safety Data Sheets (SDS) – A list of ingredients and safety information for each ink product.
 - h. Any Additional Compliance Certifications – If available, ISO, REACH, or other safety certifications demonstrating commitment to product safety and transparency.

We appreciate your prompt attention to this request, as compliance documentation is an essential factor in our decision to [purchase/distribute] tattoo ink products. Please provide the requested information by [specific date, e.g., within 14 business days] to ensure uninterrupted business relations.

If any of these documents are unavailable, we would appreciate a written explanation of any comparable compliance measures that we should consider. Please send the requested information to [your email] or [your mailing address]. If you require further clarification, feel free to contact me at [your phone number].

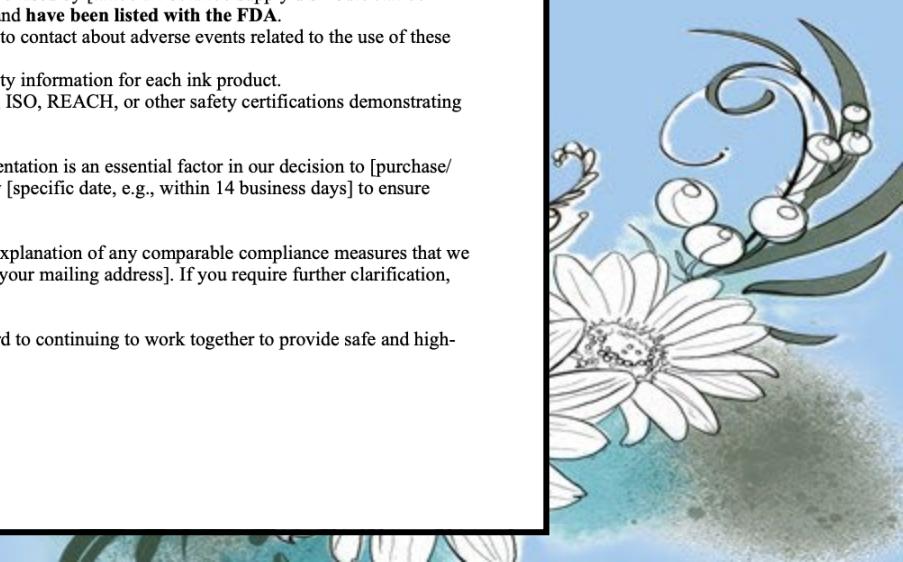
Thank you for your cooperation. We value our partnership and look forward to continuing to work together to provide safe and high-quality tattoo ink products to the industry.

Sincerely,

[Your Name]

[Your Business Name]

[Your Contact Information]



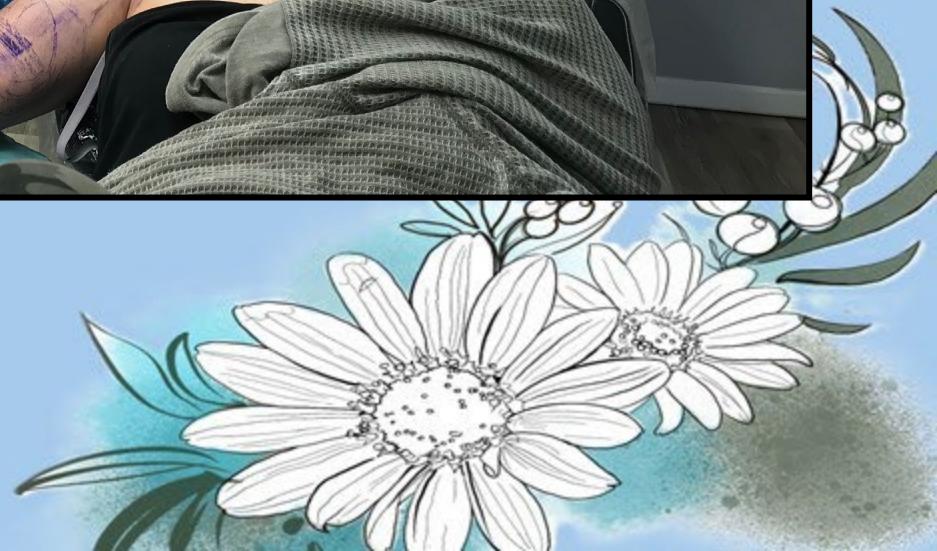
Setting the stage for a FAIR DEAL

A transparent and clear transaction between the Artist and Client

- **Ethical Standards:** What's weighing on my conscience?
 1. Client comes 1st - Public Health
 2. Amazing Body Art - subjective
- **What keeps my conscience clean as a Body Artist?**
 - Tattoos = Elective procedure: Don't want to hurt client, myself, my family.
 - Having Ink standards that assure verification of MoCRA adherence is the Minimum needed:
 - Educated: Being able to explain what/why,? recalls
 - Consider: Ingredient Allergens
 - Ink Longevity: optimal results
 - 3 components: Ink, tattoo application, skin healing



AokTattoo.com - Amy Ward in Studio

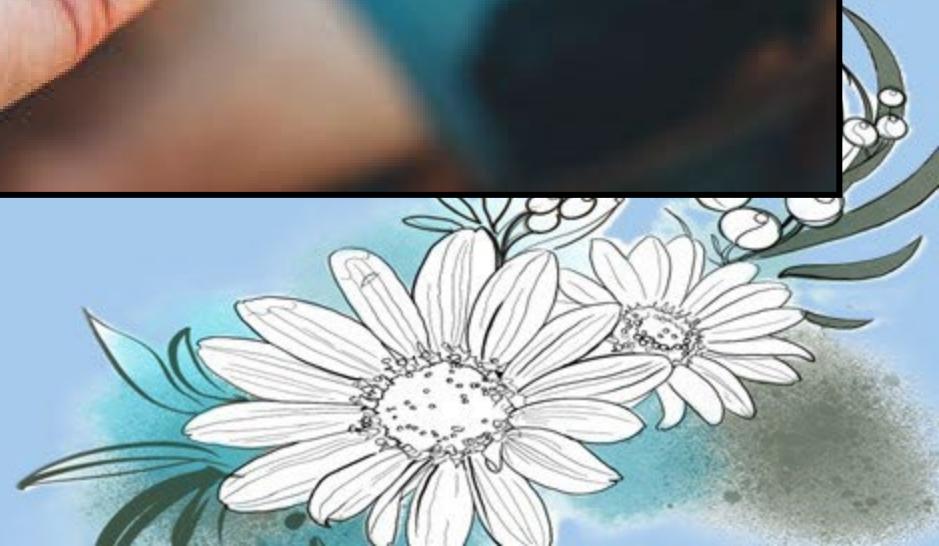


Setting the stage for a FAIR DEAL

A transparent and clear transaction between the Artist and Client

- **How can it help my Shop?**
 - Artist to client: “I have a standard for Ink.”
 - PPE standards vs. Tattoo Ink standard visibility
 - Client education = Informed Consent-
 - Right to ask: “what’s being deposited into my skin?”
 - Goal: “I can ask my licensed practitioner what their Ink standard is”
 - Tattoo Artist Best Practices & Body Art Shop Policy





Positive Impacts of Ink Standards

Be a Leader: exhibit quality control over my ink supply

- **Sets me apart : competitive advantage as a Tattoo Artist**
 - Body Art Business: Return Clients = word of mouth = more money = successful long-term
 - Better tattoo procedure outcomes, Ink longevity
 - Provides clients with what they need- to know I haven't hurt them
 - Worth whatever it takes: Monetary Cost, Client Records, Admin hours
- **Dependable SUPPLY CHAIN:**
 - Lower risk of recall of inks I use in my practice & Change control (or request a notice of change in product)
- **Public health:**
 - Protection of my livelihood, those I work with, and those that collect art from us - generational collection
 - If I can be affected in a negative way: how can I have a positive effect on the situation?
 - "Get to" not "Have to"
- **Compliance with Body Artist professional licensure requirements**
- **Liability Management:** Client has informed consent : assurance that I put their health first

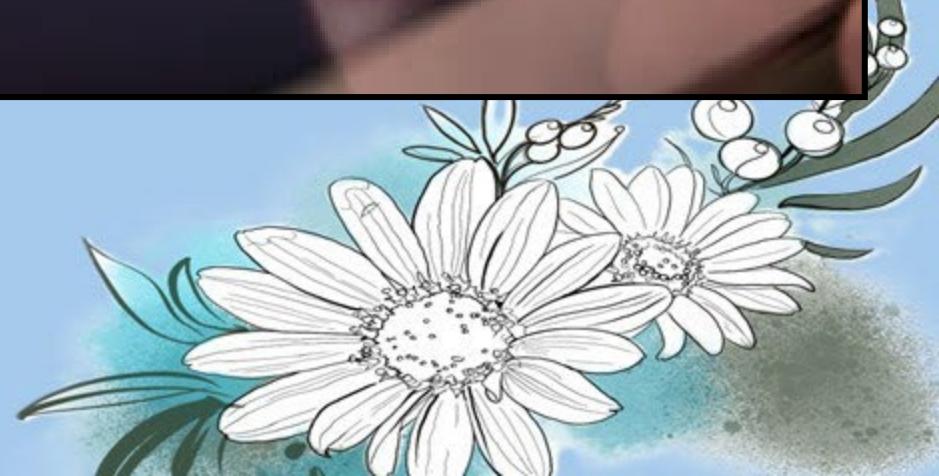
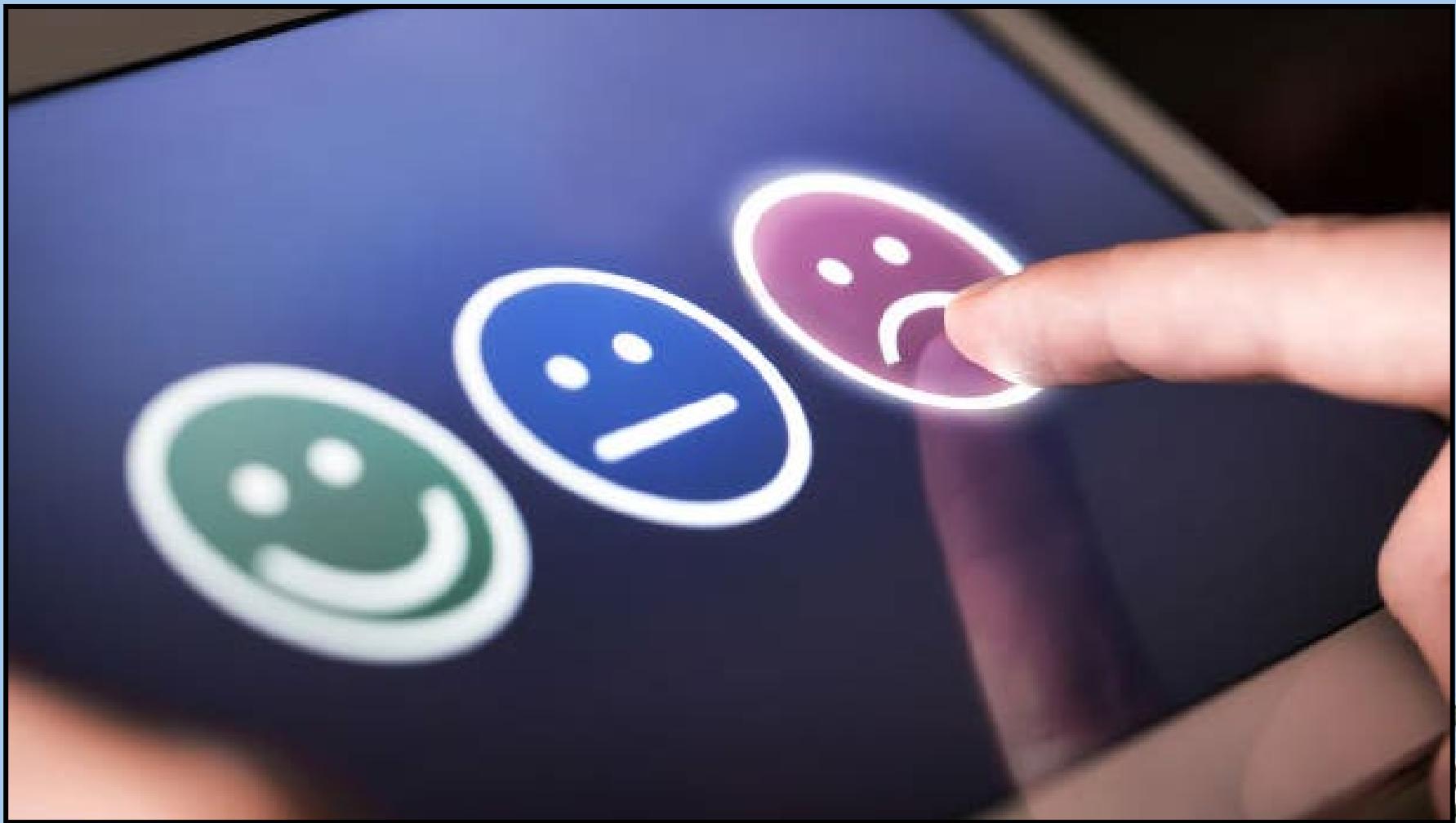


Negative Impacts of no ink standard

Don't be a casualty of your Ink mediocrity

- No Product Accountability
- Lack of control over the quality of ink
- If I use inks that are not compliant to the 7 elements of MoCRA:
 - Higher/ unmanaged risk of a recall
 - Higher Risk of Supply Chain disruptions
 - Potentially poor outcomes for clients related to inks
 - Unprofessional, SHOP REPUTATION, inspection compliance issues





Personal Ink Standard Experience

Challenges, Successes - Manufacturer Relationships

- **Personal Ink Standard** : Historically 1999-2025
 - Composition organic, ingredient list, SDS Sheet, Certificate of Analysis, REACH ink standard
 - Influential events:
 - 2003 European Council : nonbinding standard on chemical composition of tattoo inks
 - 2008: Standard revised, introducing further restrictions on chemical ingredients, impurities, and contaminants in tattoo inks.
 - 2022: EU Reach Reg., limiting the use of approx. 4000 substances - solidifying the enforcement of Tattoo Ink Standards in EU
 - 2023: NVWA launched a Euro. Enforcement action - stricter monitoring of Tattoo Ink compliance with REACH regulations
- **Challenges, successes** : Obtaining info/documentation from an ink Manufacturer
 - My Ink Standard: EU REACH compliant Ink: EU Standardized
 - Honest Broker: Proud to share and are not surprised by my request, willing to chat with me, timely manner
 - Open Mind: If an Ink supplier provides SS for ink product, I will consider it.
 - Many American Ink Manufacturers don't use a Standard, some may use internal imposed Standard
 - Indicates what an Ink Manufacturer cares about when Safety Substantiation is not a Priority.
 - Say yes, never follow through
 - Ask why I need it
 - Send one SDS sheet for the entire line of ink colors

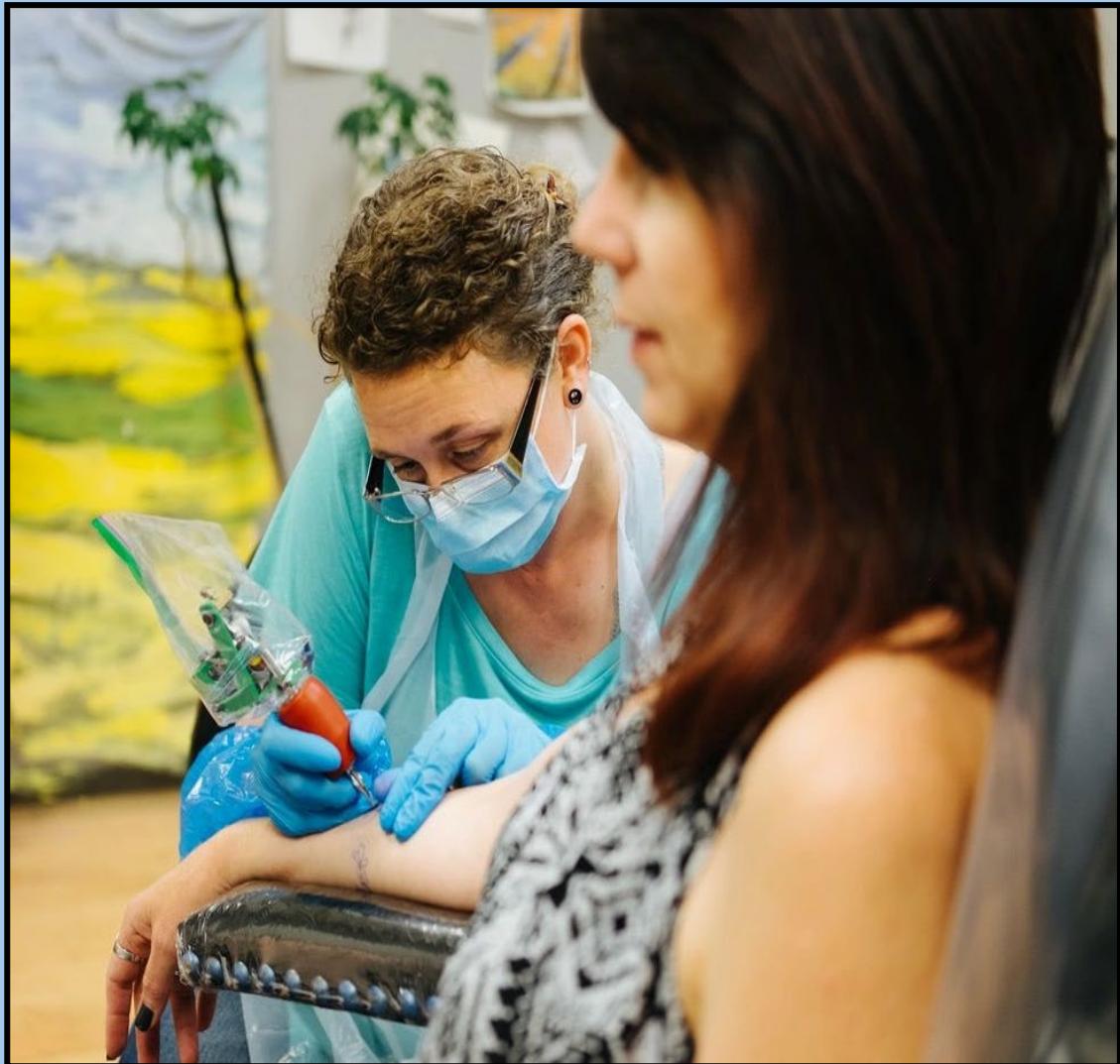


Personal Ink Standard Experience

Potential Impacts

- Trust from clientele/loyal collectors/word of mouth advertising/ referrals/ long term relationship = community building
- Ink longevity
- Traceability
- Clear conscience of serving everyone involved in the TATTOO's life
 - dependent on the ink deposited to be safe.
 - If we knew it would hurt ourselves or others, would we collect tattoos without regard, trusting someone else to verify ink Quality?
- Ethical ink Standard meets my Passion & Responsibility to use quality ink
- Client Informed consent





Generational Tattooing



Current Common Ink Discussions

Body Art Products: Quality questions to weigh what matters

1. Are ALL Tattoo inks Safe???

- Can some Inks be a risk to your health? “Not the kind I use”
- Myth: Ink has been used so long throughout history, it must be safe.
 - Has ink manufacturing changed anything about ink safety?
 - How long have adverse events been recorded?



Current Common Ink Discussions

Body Art Products: Quality questions to weigh what matters

2. Do Tattoo/ PMU Practitioners have any responsibility for the ink applied?

- Should we trust our artist to automatically use 'safe' inks ?

3. Is the manufacturer doing what they are required to do, am I taking their word for it?

- Myth: All Professional Ink is automatically safe
 - Have there been Recalls? Why? To Pro ink?
 - How can we verify/ substantiate that Risks have been mitigated after a recall?
- Myth: DIY Kits are the real risk, not recalled inks.



Current Common Ink Discussions

Body Art Products: Quality questions to weigh what matters

4. Can Body Art Product Regulation be helpful?

- Ink products are growing in use, popularity, demand
- Hazards have been identified in the manufacturing of inks
- Tattoo Industry can help create ink standards.
- Tattoo ink is validated, standardized, legitimized: Helps everyone enjoy the Art form of Tattoo/ PMU for a lifetime
- Legacy: Industry will continue to grow and Ink production in the USA will be more competitive internationally
- Supply Chain issues will be lessened, quality inks thrive



Who Can Make a difference?

Tattoo Ink can be safe: Quality discussions and relationships

- **Manufacturer/Brand Owner:** (Responsible Party) Provide GMP & SS required
- **Distributor/ Tattoo artist or PMU:** Who is the only Check between the Manufacturer and Client? :
 - Be Prepared: to have a solid answer when asked ink quality questions by your client / inspector/ apprentice.
 - Client is the reason we get to tattoo, put them first.
 - Self Regulated...Self Standardized
 - Best Practice has always been up to Tattoo Artist
 - Be the Best : because you Get to
 - Be a Professional Example : responsible and accountable, not absent and neglectful
 - Participate in AFDO BAC: as MoCRA becomes enforced and New Guidelines are formed.
 - Represent our Industry & help lead the way to regulation that serves the Body Art and Public Health.
 - Pro-active ink standards could reduce/prevent future adverse events.





Association of Food and Drug Officials

Many perspectives, one voice, since 1896.

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Body Art Committee



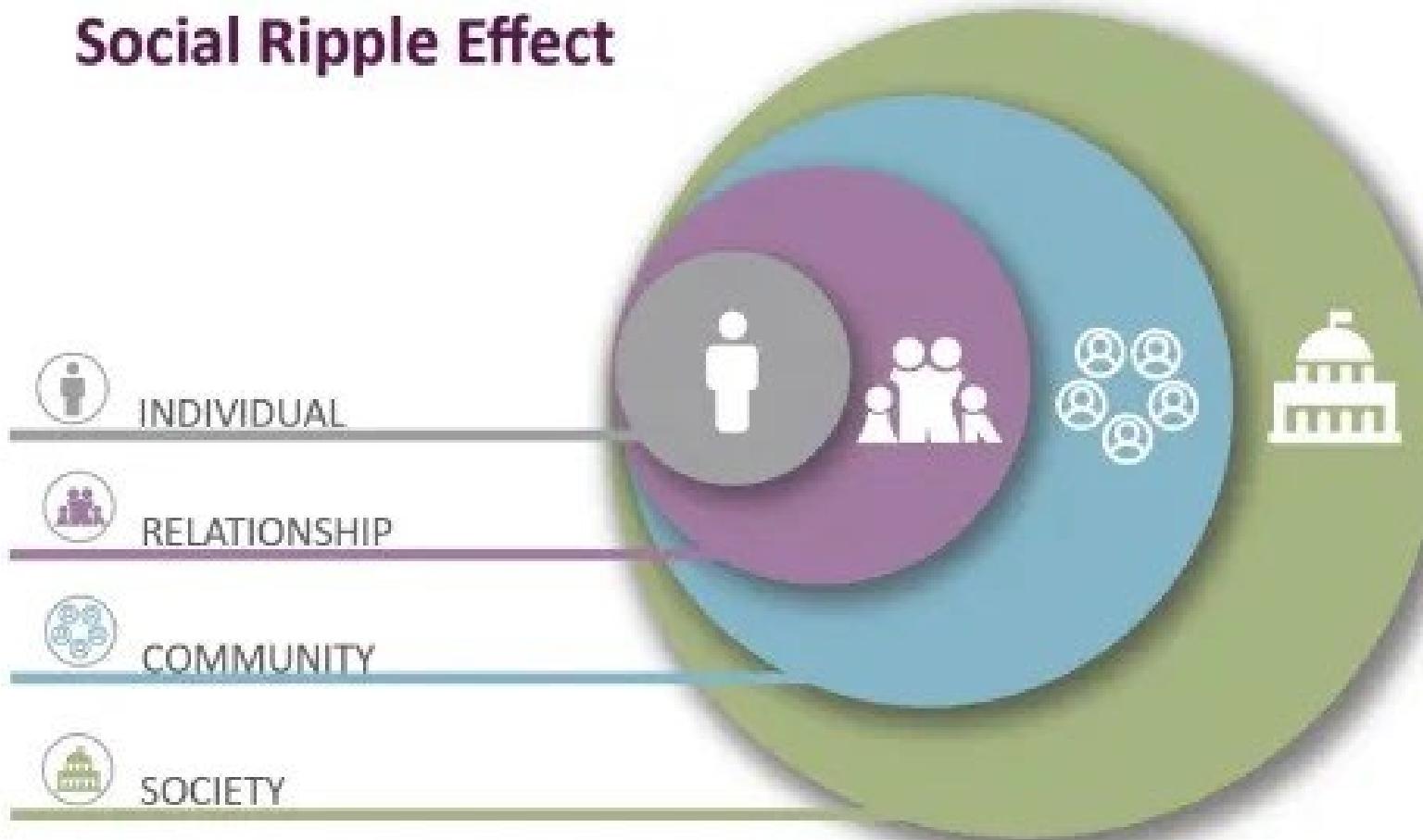
Who Can Make a difference?

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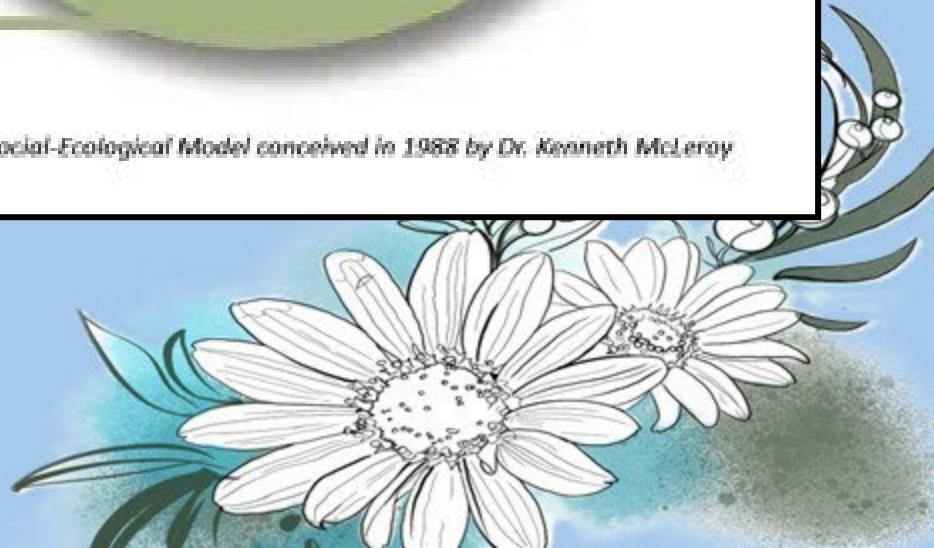
- **Client / Body Art Collector**
 - Who ultimately suffers most from Adverse Event?
 - Have you ever asked your Artist? :
 - “What’s your Ink Standard?”
 - Your life is in your hands
 - Safe ink standards start with **Consumers**
 - Public Education is Key
 - Ask people you know, Collectors & Practitioners, if they have an Ink Standard.
 - Have Quality discussions on Quality ink.



Social Ripple Effect



Based on Social-Ecological Model conceived in 1988 by Dr. Kenneth McLeroy



References:

- https://PMC11739707/#j_aiht-2024-75-3921_tab_002
- <https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2023.1279884/full>
- <https://www.historyoftattoos.net/tattoo-facts/tattoo-statistics/>
- <https://www.fortunebusinessinsights.com/tattoo-market-104434>
- <https://tattootopia.org/getting-tattoo/tattoos-hiring-2024/>
- <https://gitnux.org/tattoo-industry-statistics/>



AFDO Working Group

FDA Regulations & Guidance

- Summation of Goals and update on progress

afdo.bac.fda.rgwg@gmail.com





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Questions and Discussion

Amy Ward – amybodyart@gmail.com

Ken C. Stevenson – kcstevenson@ceutireg.com



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