Biotechnology

SECTION EDITOR

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Editorial

This article continues One Health discussions from earlier EMWA journal articles.[1–3] Earlier articles highlighted farmers' important role in One Health concerning the health of our planet. This article illustrates how biotechnology aligns with One Health and how definitions might apply. It should help many see vacant writing niches to be filled by aspiring medical writers and seasoned medical writers who want to transfer their skills. I hope it will help draw connections concerning how biotechnology is a routine part of our daily lives.

Jen

Where artisan, environmental, and medical biotechnology meet

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doi: 10.56012/nsjh8018

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It is important to highlight that biotechnology definitions of the pharmaceutical and medical device industries were established to ensure consumer safety when medical biotechnology applications were developed. The pharmaceutical and medical device industries produce biotechnology products often at molecular to whole organ levels, while artisan and environmental biotechnologies often happen at cellular to microorganism levels. Depending on the application, molecular techniques might be used in artisan and environmental biotechnology.

Biotechnology is a broad platform technology that applies to medical, artisan, and environmental applications, and it is good to have an idea of how these applications interface. Since the World Health Organization (WHO) has adopted One Health perspectives, it is becoming better known that the environment can affect the health of people and animals and *vice versa*, and this is good general knowledge to have. The European Medicines Agency (EMA) and four other European Union agencies are implementing a One Health approach – enter "European Medicines

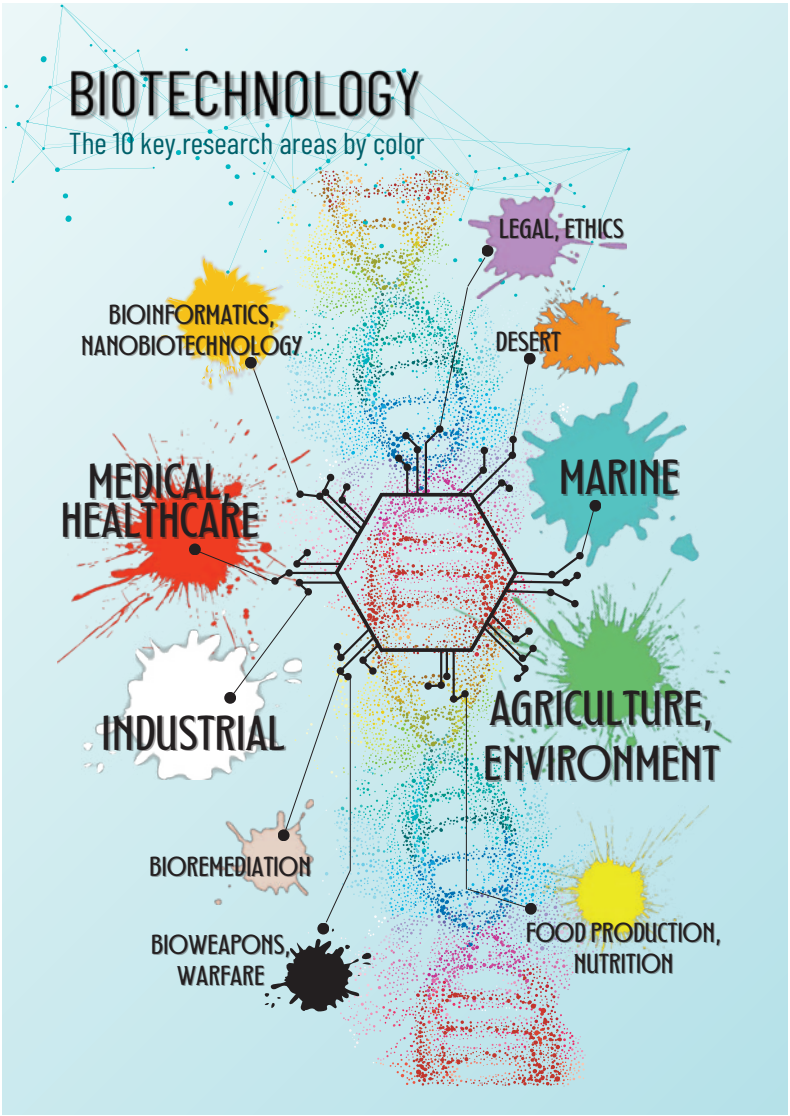

Illustration by Judit Mészáros

Figure 1. Biotechnology research areas[1]

Agency One Health" into your search browser to learn more.

As has been quoted previously in *Medical Writing*, "*Ask 10 people what "biotechnology" means, and you will get 10 different answers.*" (Figure 1)[4]

Figure 2 gives an outline of how each biotechnology might interface. Figure 2 is the product of the author brainstorming biotechnology ideas. There are many other examples where biotechnologies might interface, and some of the readership might have different opinions, which would be good to hear.

Tables 1 and 2 accompany the "Artisan" section of the Venn diagram in Figure 2.

To introduce the idea of artisan biotechnology, an artisan is "*a skilled craft worker who makes or creates material objects partly or entirely by hand.*"[5] Often, they might have a guild qualification, or their skills are recognised in some other way, like their reputations. Lucy Hargreaves described how biotechnology originated from "*ancient times when people harnessed living organisms for their benefit…*"[6] She also wrote about how "*a Hungarian agricultural engineer conceived the term biotechnology.*"[2] Since ancient times, biotechnologies have branched off as biotechnology innovations advance (Figure 3).

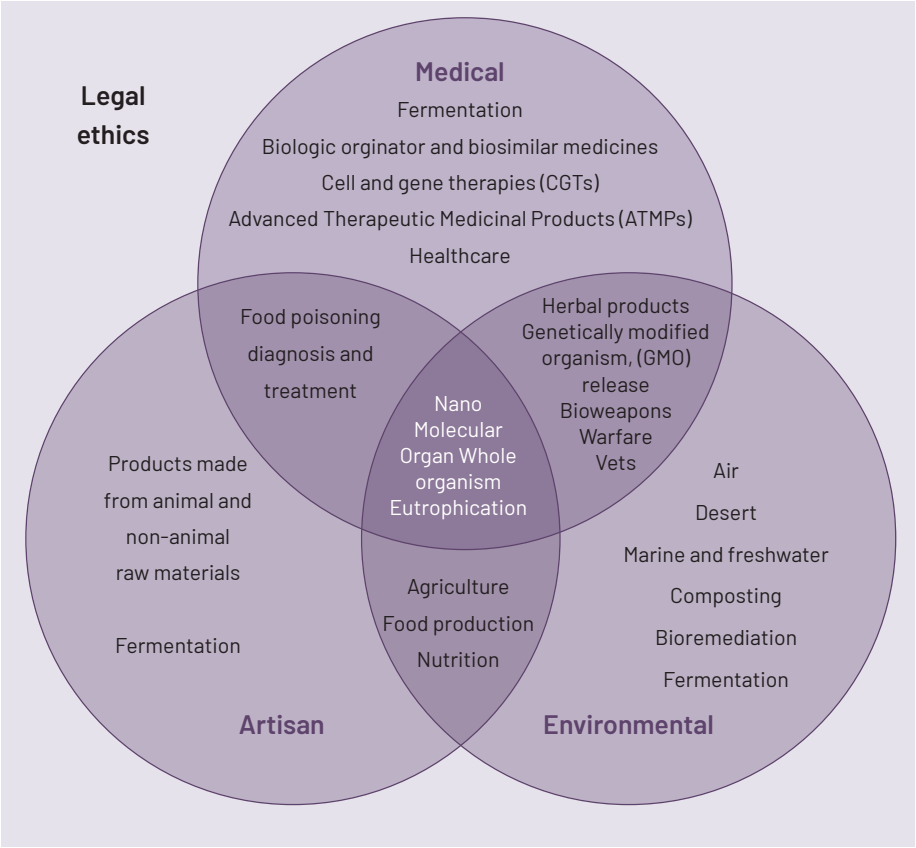

Figure 2. A Venn diagram roughly outlining where artisan, environmental, and medical biotechnologies meet

Table 1. Some raw materials used by some craftspeople

Who might use what raw product?

Some products

Animal products

- Red meat
- White meat
- Seafood
- Poultry
- Hair
- Feathers
- Skin
- Gut
- Oil
- Eggs
- Dairy products
  - Butter
  - Cheese
  - Cream
  - Milk

Non-animal products

- Beans
- Cereal stalks
- Fruit
- Fungi
- Grains
- Nuts
- Reeds
- Seeds
- Vegetables
- Wood

Tips for aspiring and seasoned medical writers

If you are an aspiring medical writer or a seasoned medical writer who wants to pivot into another area of medical writing, this is one way you could do it. You could figure out a medical angle your local biotechnologists fulfill, interview them about what they do, and write an article about it. An interview article in the EMWA journal December 2023 Biotechnology issue gives a good example of the shape you might like your article to take.[7] Think up some interview questions (Table 2), consider using a recording device to record your interview conversation(s), and either transcribe what is recorded by ear or, if you are interested in artificial intelligence (AI), figure out a way to incorporate transcription software which might help you. Most importantly, maintain a flexible approach and listen to what your interviewees say because their perspectives are very important. By the way, AI is probably more commonly known as artificial insemination in animal husbandry sectors. So, it might be a good idea to avoid using the AI

Table 2. Some questions for interviewing biotechnologists

- How is what you do sustainable?
- Why should your community buy directly from you?
- What obstacles are in the way of your business supplying directly to your community?
- Have you heard of the circular economy and how does it fit with what you do?
- Are you eligible for government incentives for what you do?
- What do you think is the best way to bring new business your way?
- How does what you do relate to what other producers do?

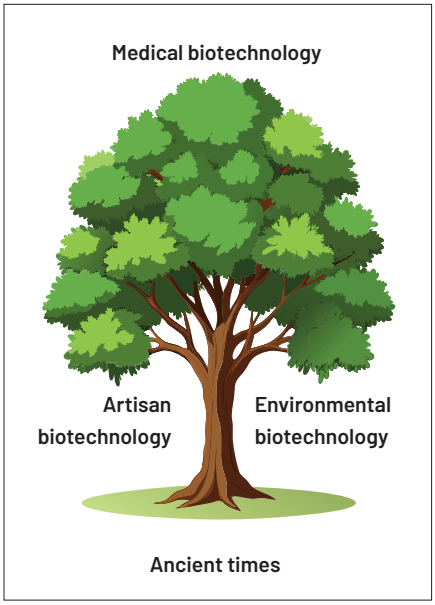

Figure 3. A schematic picture illustrating how biotechnology branched off from ancient times

acronym depending on who you interview and your article's target audience.

And the other area of medical writing I am referring to is One Health. One Health includes environmental health and is intended to lead to the better health of our planet – Gaia Theory is related and interesting to look up. The Gaia hypothesis emphasises how everything is connected on our planet which is a premise of One Health. The health of humans, animals and the environment are all interconnected.[8] Medical writing does not traditionally cover the environment's health, so there are many opportunities for medical writers here.

How is biotechnology defined?

In Europe

The European Commission says, *"…biotechnology can be used to manufacture bio-based products…"*[9] So, with this idea in mind, artisans are biotechnologists, or are they? Do governments need to change the definitions of biotechnologies to make them more straightforward to the public and help One Health filter into the global consciousness? Biotechnology fits the WHO's idea that One Health is *"an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes."* [10–12]

It is important to highlight that the European Commission uses the OECD definition of biotechnology, which encompasses artisan, environmental, and medical biotechnology, as outlined earlier in this article. The OECD definition is that *"… biotechnology applies science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials to produce knowledge, goods and services. Biotechnology can be used to manufacture bio-based products (biomanufacturing). It can also be part of the solution to address many societal and environmental challenges, such as climate mitigation and adaptation, access to and sustainably using natural resources, restoring vital nature systems, food supply and security, and human health."*[13]

The OECD definition might help people draw a connection between what farmers produce, what craftspeople and food producers manufacture, and what is on our supermarket shelves and in our homes. Most of these things are at cellular to whole organism levels rather than molecular levels.

The OECD definition is quite broad compared to more specific medical biotechnology definitions. EMA defines biotechnology as *"The use of living organisms to create or modify products, including medicines."*[14] As already mentioned, the European Commission defines biotechnology in the same way as the OECD.[15]

EMA classifies many pharmaceutical industry-regulated medical *"biotechnology"* products under biologics and biosimilars, advanced therapy medicinal products (ATMPs) equivalent to US cell and gene therapies (CGTs), and herbal products. Many medical device diagnostic products strongly utilise molecular biotechnology within *in vitro* diagnostic devices. In contrast, many non-biological medical devices might have control over the biological aspects of a patient but are not obvious biotechnology products. For example, a heart pacemaker is an electronic device that modifies a patient's heart rhythm to normalise it, so according to the OECD definition, a pacemaker is a biotechnology.

If you are an aspiring medical writer or a seasoned medical writer who wants to pivot into another area of medical writing, this is one way you could do it.

Outside Europe

Regulations and definitions change over time, and regulatory harmonisation is constant, where the rest of the world often follows in the footsteps of Europe or the USA. It is important to mention that the USA is an OECD member country, although this might change under the current US governmental administration. All the same, the OECD definition has influenced the definitions

Photo: Freepik

of biotechnology in the USA over time.

In 1983, as genetic recombination emerged in industry, the article "*Biotechnology: the view from the FDA*" was published.[16] The abstract of this article says, "*What is biotechnology? This is not a naive question. The Office of Technology Assessment has found differing definitions of biotechnology emanating from eight foreign countries and three international organisations. FDA's working definition of biotechnology is the application of biological systems and organisms to technical and industrial processes. This definition is necessarily broad. It takes in both the "old" and "new" science: the age-old techniques for making beer or yogurt as well as the most advanced uses of recombinant DNA technology. It takes in many applications, from production of enzymes for laundry detergents, to selective breeding of plants and animals, to genetic engineering of bacteria to clean up oil spills. As with any new technology, ethical issues are raised. But in the case of genetic engineering and cloning, many of the primordial fears of man concerning the power of science are awakened.*"

So how many biotechnology definitions are there today? In 2017, the FDA published a 74-page document based on challenges faced by small and mid-sized businesses navigating various industry regulations.[17]

Photo: Freepik

Artisan and environmental biotechnology versus medical biotechnology

Biotechnology as a subject can be very confusing partly because it is a platform technology that can be broadly used, so pigeonholing it to define it is difficult. Many university courses that contain microbiology modules teach that biotechnology includes bread making, cheese making, and brewing, which are considered ways to make artisan products (note that these have a fermentation process step). Artisan products generally contain bio-based ingredients grown during agriculture (Table 1). Artisan products can include a fermentation process, such as steps like in cheese making, but they might not have one like in weaving. Agriculture pertains to the environment, and, as the WHO points out, the environment's health can affect human and animal health. Other university courses like biomedical science do not necessarily go into the details of "*environmental biotechnology.*" However, biologic and biosimilar drug product manufacture has a fermentation process step as well. So fermentation is used in artisan, environmental, and medical biotechnology, but each fermentation process is nuanced depending on the application.

The WHO describes One Health as *"an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes.*

To me, artisan biotechnology is where a skilled craftworker manufactures a product from a biological raw material; environmental biotechnology is applied in the environment to make it healthier; and medical biotechnology improves the health of humans and animals. So, the WHO's take on One Health is causing me to write about how environmental biotechnology, including agriculture and artisan biotechnology, might affect human and animal health. Environmental biotechnology is traditionally outside the scope of medical writing.

Final remarks

Biotechnology used in pharmaceutical and medical device production is a small proportion of the biotechnology used on the planet. And biotechnology is already used by people who don't always realise it. Figure 1 helps illustrate these statements.

I think connections between biotechnology and how it impacts everyday life can and should be drawn but is this medical writing? In addition, it is important to know that biotechnology might be animal or non-animal-based. Biotechnology should not be feared.

Acknowledgements

The author wants to thank everyone who has an opinion on biotechnology.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by her employer or EMWA.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Jen Bell went to agricultural college when she left school. Then, for a few years, she travelled and did seasonal work on farms, in orchards, and in factories. After that, she continued her life science education. She worked in pharmaceutical and medical device manufacturing and distribution quality management roles from 2010 to 2018. She is interested in One Health which is concerned with threats to the animal-human-environment interface. Jen is passionate about the potential for biotechnology to improve lives. Today, she is a biotechnology consultant and freelance medical writer.