Personalized Nutrition

*It’s Time for Personalized Manufacturing*

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Introduction

The medical community has long recognized the inherent uniqueness of patients in terms of age, race, weight, prevalence of disease in specific families and ethnicities, blood transfusions, organ transplants, and variable responses to medications. Yet medical practice, in general, uses broad treatment regimens for this heterogeneous population instead of unique treatment approaches for individuals. Increasingly advances in medicine, using DNA as the scientific underpinning, have shaped the adoption of personalized medicine from a concept to the pillar of every life science and healthcare company today.

Diet is recognized as a significant modifiable risk factor in the development of chronic diseases such as diabetes, cardiovascular disease, and certain cancers [1]. According to the CDC, 6 in 10 adults having at least one lifestyle induced chronic disease [2]. Based on this epidemic one can conclude that the current public diet recommendations and current food offerings have been inadequate in providing solutions for people to eat in a manner to avoid these preventable diseases. Emerging scientific evidence continues to demonstrate that individuals not only need personalized medicine to treat illnesses, and more importantly, personalized nutrition, is likely to contribute to a full healthy life [3]. The science supporting personalized nutrition is complemented by market analysis, as consumers become more receptive to personalized diet advice as opposed to following the general food guidelines as is shown in several studies like the Food4me study [4].

In recent years, personalized nutrition has become more than a trend as a new generation of consumers are demanding personalized nutrition to replace the confusion driven by mass marketing of “one size fits all” nutritional products. The convergence of technology and increasing consumer interest in nutrition and wellness combined with increased access to nutrition and wellness information is leading to new health products and services focused on personalized diet and convenience. By utilizing simple online techniques like questionnaires and analyses of individual lifestyle factors, coupled with more robust data from wearable devices, DNA analysis, blood biomarkers, and microbiome profiling, personalized nutrition strategies are evolving that can result in products that are better formulated to match an individual consumer’s lifestyle, genomic predisposition, and metabolic needs than anything currently available.

To meet the plethora of diverse needs of individuals, a fundamental shift in the infrastructure of food and nutrition industries that supports health and wellness is needed. Consumer Packaged Goods companies (‘CPGs’) will need to adapt their product marketing by providing personalized recommendations driven by the individual consumer’s profile data. CPGs must also recognize the need to
provide truly personalized nutrition product offerings that address specific health needs that are difficult to achieve by “one size fits all” product formulations. Prevention and wellness-based product offerings also need to rapidly adapt to a person’s changing lifestyle and healthcare needs based on data and feedback, for example changing needs that come with age, reproduction, illness, or changes in activity.

The mass production paradigm needs to change to meet the onslaught of scientific information and changing consumer desires. A current example of such change can be seen in the use of online [4] decision-making questionnaires and individualized packaging, such as PillPack and Persona\textsuperscript{TM}, each providing a simple type of personalization that assembles an assortment of pills (medicines and supplements, respectively) into a simple package. These solutions, although aiding consumer convenience, are plagued by the “pill burden” created by multiple pills needed to meet the appropriate doses and multitude of ingredients. Many studies have demonstrated that increasing the number of pills taken daily leads to low adherence and is not suitable due to swallowing issues to certain populations like the elderly and the young [5].

Not only has nutrition science identified individual differences in micronutrient needs, but also individual differences in responses to macronutrients and different foods have been observed [6] [7]. To personalize both macro- and micronutrients at doses that provide benefit, more convenience as well as more palatable forms of delivery are needed to improve consumer acceptance and consumer adherence of personalized preventive nutrition.

This paper will present an innovation for on-demand adaptive manufacturing processes, developed by Panaceutics Nutrition. This software driven robotic technology can quickly input consumer information, then build a 14-30-day supply for an individual containing both macros and micronutrients produced in an appealing, ready to eat, easy to swallow form. The method makes ready to eat custom fortified food products that are shelf stable without refrigeration, so that they can be delivered direct to the customer (DTC). This innovation in manufacturing methodology updates the mass production approach that has driven industry to only make “im-personal” nutrition. This new flexible manufacturing platform promises to make personalization economical and widely available to large populations. This system has already shown in limited production that it can be adjusted on a frequent basis, either to meet the changing needs of an individual or to meet the changing scientific understanding of nutrition. This patented manufacturing platform represents a novel paradigm shift of how nutrition can be personalized to meet the ever-changing needs of people.

**Actionable Approaches to the Science of Personalized Nutrition**

*“How do you take these data and make them actionable for the person in the moment?*  
_Nathan Price, Co-Founder of the innovative wellness company Arivale, when describing the 100k Wellness approach to collecting data and creating Personalized, Dense and Dynamic Data Cloud (PD4).*

Traditionally, nutrition science was based on the presumption that everyone absorbs and metabolizes nutrients similarly and differences in daily requirements was mainly based on age, gender, pregnancy, and breast-feeding status. However, current evidence has demonstrated that individuals have variable metabolic responses to nutritional ingredients and diets. The differences are due to an individual’s genetics, lifestyle, gut microbiome, epigenetics, environmental exposure, current nutritional status [8]. Current approaches used to study these inter-individual response to diet include many –omics” technologies such as genomics, metabolomics, proteomics that are integrated with systems biology approaches [9]. These “big data” approaches will allow for integrating and analyzing complex datasets to
generate dietary recommendations [10]. Ultimately using machine learning and Artificial Intelligence (AI) systems, this enormous amount of data will be used to build an individual’s profile to help improve health through dietary interventions. However, as scientific studies continue to elucidate these complicated responses to dietary intervention, a pragmatic and tiered approach can be implemented to begin to improve dietary recommendations to individuals.

1. Surveys and diet trackers

Personalized approaches can start simply with questionnaires, move to genetic analysis, then to blood based biomarkers, microbiome analysis, and finally metabolomics to guide health decisions. This step wise approach can help transition people from getting information about themselves to using it in their daily lives. In addition, use of periodic repeat testing and wearables for constant monitoring can provide feedback for effectiveness and used to adjust diet parameters such as ingredients and dosage. For instance, one can use simple survey questionnaires and monitoring with food trackers for an individual to determine nutrients that are often deficient such as EPA/DHA, Vitamin D and fiber [11]. This survey approach is a low friction, non-invasive method and currently being implemented by many digital apps and personalized coaching companies. In the Food4Me study, personalized advice was given by nutrition researchers using decision trees based on an individual’s preferences, goals, ambitions, and current lifestyle. This personalized advice was ultimately followed longer than general guideline advice. Another approach is to use personalized nutritional “crowd coaching” via internet and apps to connect customers to registered dieticians. Also, companies and providers can generate diet recommendation algorithms that can provide support and recommendation via apps and chatbots. Although survey and tracking are easy paths to personalizing diet, it is fraught with assumptions about individual metabolism and inaccurate reporting of what people say they eat and do [12]. New technologies, like food recognition apps, could provide a more seamless tracking and input system for future survey and tracking leading to more robust personalization.

2. Nutrigenetics/nutrigenomics for important individual metabolic roadblocks

The promise of using genetics for medicine and nutrition is the current foundation for personalization. Nutrigenetics and nutrigenomics, defined as the “science of the effect of genetic variation on dietary response and the role of nutrients and bioactive food compounds in gene expression”, is a way to provide genetic based personalized recommendations for diet [13]. DNA can easily be acquired from a saliva sample and analyzed by arrays, PCR, or sequencing. Many DNA diagnostic companies are offering services to provide information about family history, health risks, and nutritional guidance. By using nutrigenomics to identify possible “roadblocks” in metabolic pathways one could make personal recommendations using this personalized information. For instance, single nucleotide polymorphisms (SNPs) have been identified for several genes such as the MTHFR, FUT2, and NBPF6 genes that could impact an individual’s vitamin B2, 6, 12, and folate status [14]. In addition to these, other SNPs have been identified for Vitamin A, C, D, E and choline [14]. However, typically these SNPs simply identify a possible risk to have altered metabolism and therefore and do not provide actual
current blood and tissue levels of these vitamins for individuals. Genetic risk for other phenotypes such as high triglycerides and cholesterol levels, response to fats, and disease propensity such as diabetes, obesity, coronary artery disease can all be used to structure a more personalized diet [14]. As more complete polygenic risk scores evolve and are validated this method may provide a relative low threshold for the consumer to get a personalized recommendation [15].

3. Direct quantification of blood biomarkers and nutrients

Ikeally quantifying nutrient blood levels using standard commercial lab tests or direct to consumer test at home test to make a recommendation is the most preferred method. Nutrient status evaluation is the key to knowing if someone has a deficiency or has sufficient blood levels. Providing supplementation to deficient individuals can improve their health status, however providing additional supplementation to normal levels will show little benefit and may in fact be harmful. For instance, providing iron supplementation to people with hereditary hemochromatosis, an inherited disorder of abnormal iron metabolism, can result in toxicity to glands and organs as iron accumulates [16].

Acquiring blood through venipuncture, finger pricks, or even the painless blood draw technology developed SeventhSense BioSystems, is an inconvenience that many consumers may not willing to purchase or experience. In addition, there is not always a direct correlation of the current blood concentration and the amount of supplement needed to correct that deficiency. A recent review of vitamin pharmacogenetics highlighted the some gene polymorphisms that can affect the absorption, distribution, metabolism, and excretion (ADME) of vitamins such as Vitamin D, C, K, E, and folic acid [17] These genetic variations are clearly observed with Vitamin D, when the dose administered can result in as much as a 10-fold variation in serum levels between individual [18]. Other nutrients such as lutein and carotenoids have also been shown to have highly variable bioavailability with a genetic linkage and other factors. For instance, highly variable postprandial lutein bioavailability is determined by at least 15 SNPs and premeal lutein status, while inter-individual variability in beta-carotene bioavailability appears to be partially modulated by a combination of SNPs in 12 genes [19] [20]. In short nutrient bioavailability can be highly variable and none of this variation can be captured by an umbrella recommendation. A need for personalized dosing and feedback is key to personalization.

4. Disease risk prediction using genetics and biomarkers

Another way to implement personalized nutrition is to use genetic and biomarkers as predictors of disease risk to generate personalized supplementation and diet recommendation. This approach of using a combination of gene variants of candidate genes [mostly single nucleotide polymorphisms (SNPs)] and plasma lipid blood levels as a predictor of traditional cardiovascular disease (CVD) risk has been used in the past to make general recommendation for diets, such as recommending the Mediterranean Diet, DASH diet, the USDA food pyramid, etc. It has also been used extensively to recommend cholesterol lowering and antihypertensive medications [21]. In addition to generalized diet recommendations to reduce CVD risk, there has been a consistent message to increase the consumption of fish in one’s diet, or to supplement with what is considered the CVD protecting component, fish oils or the purified omega-3s fatty acids. [22]. However, results from clinical trials of adding fish oil or omega 3s supplementation have not consistently reported significant CVD event reduction. Part of the conflicting data could be due to different types of fish oil or Omega-3 used in the clinical trial, and/or the assessment of a fixed daily dose of omega-3 versus the measurement of omega-3 blood levels achieved in each patient [23]. Understanding current status is critical because wide variability in individual blood levels achieved in response to a fixed dose of omega-3 and fish oils has been reported. For instance, a dose of have 1g/day of EPA increased mean EPA+DHA
levels from 3.6% to 5.4%, but failed to increase the levels to the goal of 5% in greater than 16% of patients [24]. Individual variability response to such a common dose could leave a substantial number of patients at elevated CVD risk due to failure to achieve a therapeutic EPA+DHA blood level. The blood EPA/AA ratio is also a clinically relevant measurement and has substantial individual variability in response to a fixed dose as it is an indicator of the potential inflammatory status of a patient [25]. In addition, the variability is related to in part to genetic differences in fatty acid metabolism and part due to lifestyle (gene-diet interactions) such as replacing dietary saturated fats with omega-6 linoleic acid containing oils [26]. In other words, increasing omega-6 can have a negative impact on the biosynthesis of omega-3 fatty acids as they compete for the same biosynthetic enzymes encoded by the FADS and ELOVL genes [26]. The FADS and ELOVL2/5 gene clusters that are highly polymorphic, ancestral based, and are associated with numerous phenotypes such a CVD, inflammation, insulin resistance, and memory. Use of an individual’s data acquired from biomarkers could improve the recommendation for long chain polyunsaturated fats in the diet and ultimate health outcomes [26]. However, even with that complexity, simple approaches to predict and personalize an omega-3 index red blood cell response to therapy can depend be done on simple measurements such as body weight. Flock and colleagues investigated the individual omega-3 index response to 0, 300, 600, 900, and 1800 mg/d of EPA + DHA supplementation and reported that adding weight and adding additional factors such as baseline omega-3 index, age, gender, and physical activity improved power of prediction of treatment response to 78% [27]. In essence, using health risk factors combined with genetic information and phenotype data like age, weight and gender can provide improved recommendations for individuals needing preventative treatment.

5. Microbiome predicts response to diets

It is now known that the microbes that live in the human gut are involved in virtually all aspects of human health [28]. They can synthesize vitamins, amino acids, neurotransmitter and harvest energy from our diets. They help with digestion and strengthen the immune system. An unhealthy microbiome has been implicated in allergies, arthritis, asthma, autism, colon cancer, several infections, diabetes, inflammatory bowel disease, obesity and many other diseases [28]. In addition, diet can directly or indirectly influence the gut microbiota, and studies have shown that this response can be rapid with changes observed within 1–3 when the modifications are “large” such as the all-animal or all-plant products diet or large increases/decreases in fiber days [29]. The human gut microbiota varies across the lifespan, geographical regions, living arrangements, disease and even exercise [28].

Other studies have demonstrated that glycemic responses to bread and real-life meals can vary greatly across individuals and that this response can be predicted by an individual’s gut microbiome [30] [7]. With the human microbiota being characterized by extensive inter-individual variation, and with genetics a significant contributing factor, and it is now becoming clear that the composition of an individual’s microbiota will determine how it responds to dietary components such as macronutrients, fiber, and polyphenols. In this regard, understanding what ‘responding’ and ‘non-responding’ microbiota look like is essential as well as how to convert a ‘non-responder’ into a ‘responder’ [31]. The goal of personalized nutrition is to include the microbiome as part of the person and recommended diets and possible nutritional therapies that positively impact the microbiome to improve health [32]. Building on this symbiosis, evidence has emerged that indicate that feeding the microbiome with specific oligosaccharide fibers can increase beneficial metabolites like the short chain fatty acids acetate, propionate and butyrate [33]. Using microbiome profiling provided by companies like DayTwo, Viome and others could be used to produce personalized nutritional products to feed the good microbes and starve the bad ones or even introduce new ones through probiotics.
6. Metabolomic phenotyping to predict diet

Using metabolomic analytical techniques researchers can measure thousands of metabolites and create rich data troves for deep understanding of physiological responses. However, this approach is, highly complicated, expensive and just adds to the confusion of personalized diet recommendation until the data can fully understood. However, pared down approaches like “Phenotypic Flexibility Testing” using standardized nutritional stress tests can be quite useful in diet recommendations. Using the Oral Glucose Tolerance Test, Lipid Tolerance Test, and Protein Tolerance Test and measuring a subset of metabolic markers revealed inter-individual variation in both healthy subjects and T2D subjects [6]. While this approach of identifying metabolic phenotypes or “metabotypes” is still emerging, the approach has begun to identify decision trees that can help provide diet recommendations that improve metabolic markers and these approaches seem to benefit at risk individuals the most [34]. These initial studies have been expanded by an increasing number of longitudinal studies using big data approaches that are identifying actionable health markers to help provide recommendations for personalized diets and supplementation prior to disease progression [35](https://joinzoe.com/studies/predict-2). Together these studies suggest that personalized diets can be created to personalize micro and macronutrients formulations to improve health status.

**Consumer Technology and Information Driving Personalization**

As much as scientific studies are supporting a need for personalized nutrition, a key driver to implementation is the desire of the consumer to achieve their health goals. With the cost of healthcare increasing, more consumers look on the internet for answers that address directly to their needs and beliefs for disease treatment and prevention. While scientists are debating studies and trying to agree to treatment guidelines, the introduction of health and wellness technologies into the marketplace has created tribes of biohackers and diet adopters. The rise of companies paving the way for personalized nutrition like 23&me, Orig3N, Habit, DayTwo, Genopalate, and InsideTracker, offering information to individuals is growing every day even if scientific validation is lagging. Consumers have access via companies to evaluate everything through home and/or clinical grade blood tests, DNA analysis, microbiome analysis, activities trackers with integrated heart rate and blood pressure monitors, body imaging like DEXA scans, carotid artery ultrasound, and even concierge full-service health evaluation from licensed medical practitioners. Further using continuous glucose monitors developed for diabetic patients is now being used these “biohackers” to measure blood glucose in response to their meal choices. This adaptation may may push this technology into mainstream as well. Not only is whole body analysis being done, but skin analysis and eye analysis have been linked to personalized solutions. For instance, macular pigment optical density (MPOD) testing is a non-invasive way to know the lutein and zeaxanthin levels in your eyes and is being offered as a service(https://www.eyepromise.com/). So, with over 165K digital health apps, the consumer can easily measure, enter, and track their activities and diet to meet their health goals. The ERA of the QUANTIFIED SELF is here and growing. This has created many opportunities to develop personalized products from this wealth of information that meets an individual need. Astonishingly, the Global Personalized Nutrition and Wellness Market is set to reach a value of $130B in next five years (Grand View Research).
Artificial Intelligence to Integrate Data & Recommendations

Unlike the goal of personalize medicine to provide a “magic bullet” of a right drug to right person, personalize nutrition is using a complex set of ingredients including macronutrients, micronutrients, polyphenols, fibers, that provide both calories and co-factors for a healthy metabolism. The historic reductionist approach to identify a specific isolated nutrient to provide preventative health strategies is not sufficient to address the complexity of diet habits to influence a myriad metabolic risk factors [36]. The focus on isolated ingredients like omega3’s, calcium, vitamin D, etc. has led to more confusion on what constitutes a healthy diet and distracts from an integrative multicomponent approach [37]. For instance, current research supports fish as part of a part of healthy diet and is considered to be key component of a cardioprotective diet. This has driven the scientific reductionist and the market to prove that omega-3s are the key component to these protective effects. After many clinical trials and a plethora of products on the market, the data is still unclear on the health benefits of omega-3 fatty acids as a supplementation. The truth may be that eating fish provides several important other ingredients in addition to omega-3 fatty acids such as vitamin D, iodine, selenium and protein that may contribute to the healthier overall profile [38]. Also, by eating fish one is also choosing not to eat foods like red meat or processed foods that may similarly contribute to cardiometabolic risk factors for that meal. Ideally, data suggests that people should eat as few processed foods as possible to meet their dietary requirements. However, even this is problematic due to the decreased and changing concentrations of nutritional components in food due to current farming practices [39] [40]. In short, the goal for the future of nutrition and particularly personalized nutrition should be to provide recommendations that are complete solutions in terms of whole foods, including fortified foods, and supplementation that match the individual's needs and goals.

These technologies that are measuring and analyzing a multitude of data is leading to the exponential growth of complex data. The key to integrating all this data into meaningful diet recommendations and personalized products is obviously software platforms that leverage telehealth, complicated algorithms, and machine learning [41]. Multitude of companies such as OmadaHealth and Noom use behavior science and tele-nutrition or apps to integrate diet, weight, and exercise tracking to personalize health habit changes. Based on the first major advance in utilizing microbiome and machine learning diet prediction work from the Weizmann Institute of Science, DayTwo has built a platform that allows customers to predict which foods are most likely to predict a spike in glucose. This and several other studies have demonstrated that machine learning architecture with large scale clinical data are capable of using the inter-individual variable responses to an assigned diets to create more personalized diets for consumers [36]. However, many challenges to integrate this data are still in the near-term horizon before this can be fully implemented [36].

Health Behaviors are Personal

While future AI will need to incorporate even a broader range of ever-expanding research and clinical data to complement the individual data around diet, the key to making this accessible to the masses is not only personalization, but simplification, and to make it pleasurable enough to change habits. While some people are motivated to change their unhealthy lifestyle due to an adverse health event to them or
their family, most people often do not make sufficient long-term changes to sufficiently improve health [42]. For personalized nutrition to be successful, the recommended lifestyle changes and accompanying products need to facilitate behavior change for long-term adoption. Personalized Nutrition must use approaches like the Fog Behavior Model (BFM) that motivate, allow, and prompt people to succeed in their health behaviors [43]. Recognizing that these behavior changes are personalized as well as the products and services is a key to long term success. Using personal information such as genetic information or other health drivers can be used to motivate, using this complex information to make a product for an individual allows the consumer to comply, and by using feedback data or new science could be a way to continue to prompt long term use. At the end of the day the product needs to taste good and be easy to use. Panaceutics platform delivers personalized nutrition in a variety of appealing flavors such as apple spice, tropical fruit, and berry.

Manufacturing Personalized Nutritional Products

“A key issue facing for [manufacturers]- possibly the biggest barrier to personalization is seemingly contradictory goal of producing individualized products on an industrial scale.” NutraIngredients.com, February 5, 2018

Panaceutics Nutrition set out to change the manufacturing paradigm for dietary consumer products to meet the oncoming personalization era. The patented platform that Panaceutics has designed changes the manufacturing from making “one size fits all” products, that sit on shelves for months, to making products on-demand for an individual that are shipped direct to the consumer (DTC) [44]. Regardless of whether the individual data acquired is lifestyle information, genetics, microbiome, metabolomics or a combination, our cloud-based personalization software tools flexibility allows custom formulation of a nutritional product by a healthcare practitioner or automatically recommendations via proprietary algorithms. In 2-3 minutes the on-demand platform builds a 14 to 30 day supply in a “pill free” fruit puree smoothie format from a library of high-quality ingredients, including macronutrients, (protein, fiber, fruit, vegetables), micronutrients (vitamins, minerals), healthy fats, nutraceuticals, and plant or herbal extracts. Consumers can choose daily nutrition products that are shelf-stable and packaged as either a 2oz “smoothie shot” or 4-6 oz smoothie drink. These tasty, easy to swallow delivery formats allow our customers to consume on the go, or incorporating our product into shakes, or combined with yogurt, or simply as a pleasing alternative to multiple pills. In addition to...
building a supply for an individual (n=1), the platform can run the same formulation repeatedly and build micro batches from ten to a few thousand. This adoption of the technology can help “microsegment” the market when n=1 product is not needed.

Another advantage of our personalized on-demand process and DTC platform is the use of a patented flash pasteurization microwave process in an acidified food that allows accurate dispensing of ingredients. As opposed to the current industry practice of adding overages of thermal and shelf life sensitive ingredients, the Panaceutics process results in a very accurate quantity of these ingredients in the final product. Internal processes and shelf life studies have demonstrated that concentration of these ingredients is within 5% of initial label claims from beginning to the beyond use date. (internal GMP data). For personalized nutrition to move to precision nutrition the delivery of accurate doses is critical. It is no use for a consumer to buy a Vitamin D or other nutritional product off the shelf that may have anywhere from 8-177% of the label claim as seen in one survey of products on the store shelves. [45]

Panaceutics Value Proposition Over Competitor

“Focus on something the customer wants and then deliver it.”
– Frank Perdue

In a 2-month market trial of customers who had purchased and used our product, an independent marketing research team found that: 88% WANTED to continue using OUR PRODUCT everyday

Other technologies are emerging to attempt personalized manufacturing for instance, Multiply Labs, is seeking to develop 3D printing to produce a personalized pill, but this technology will be limited by the size and dose of a pill, and does not address macro-nutrition. Pills with high enough doses to be effective will be too large to swallow leading to a smaller multiple pills approach. This “pill fatigue” will ultimately lead to lower adherence and reduced efficacy [5]. Others are seeking to deliver personalized meals but have yet to solve the operational challenges of producing an “personalized meal” and the distribution issues keeping meals fresh for large scale delivery.

Panaceutics value to consumers is to produce a unique, high quality, affordable nutrition, non-pill, tasty product that considers the individual profile of each customer, gives them simple-to-understand choices, and adapts to changing stages of life. We believe people want to be healthy but are overwhelmed and frustrated by the constant flood of information from marketers and the media. This “information overload” leads to confusion as to which nutritional products consumers should use, and at what dosage. Panaceutics eliminates this confusion by providing data-driven assistance to deliver a product that is tailor-made for each individual. We believe this DTC product will also drive customer loyalty or “stickiness,” because the product will not be available from traditional mass marketers and can be easily refined from batch to batch.

Panaceutics process and delivery formats can handle high doses of ingredients like omega-3s fatty acids which is needed to be dosed in grams quantities to have CVD protective effects [25]. In addition to specific supplements the product format can have significant amounts of fiber to improve digestive health as well as protein quantities to improve muscle metabolism [46] [47].
Panaceutics patented manufacturing platform is small scale and modular which allows for production expansion to grow in response to demand and for facilities to be physically distributed strategically close to customers. It is anticipated when fully optimized each manufacturing line would produce 10-12K personalized 30 day orders a month. So, a relatively small facility, in the 12-15K square range could accommodate 5-8 lines, and thereby producing roughly a million personalized orders a year. Also, this small scale modular distributive manufacturing approach provided opportunities to address geographical regional differences for both nutritional needs and taste preferences as well seen across the world. Another benefit to small batch on-demand manufacturing is not having to carry large amounts of finished goods inventory for extended periods.

ON_DEMAND PERSONALIZED MANUFACTURING PLATFORM

- Gravimetric and volume measurement of each ingredient dosing
- QR code to ensure correct ingredient, density, and import of full cGMP log for API
- Built-in Clean-in-Place infrastructure to eliminate batch-to-batch cross-contamination, ensure cleaning cycle
- Recording of process variables for each QR tracked batch
- Real-time sensing of pH, conductivity, flow rate, temp of each batch

Personalized Product contains macro/micronutrients including other supplements.
Challenges to Personalized Nutrition

The challenges for personalized nutrition to become a mainstream approach are mainly based on the premise that consumers and healthcare providers want products they can trust and that also offer real, proven benefits, at prices that provide value to them. Defining what those benefits are provides many opportunities to personalize approaches which means different things to different people. Consumers may want personalized products with functional ingredients that help them with their lifestyle goals such as weight loss, exercise, sleep, focus, energy, etc. Medical professionals will want to help their patients with personalized preventative products for cardiovascular disease, diabetes, osteoporosis, and digestive health. Defining the benefits people are seeking is as personal as defining the ultimate product and service.

A key technical challenge to providing these trustworthy products is data integration and analysis into meaningful decision tools that create recommendations for an individual. Leveraging public and private scientific databases in conjunction with utilizing current recommendations can facilitate the process of providing these recommendations. Leveraging machine learning and AI to improve those recommendations is the only way to handle this huge number or permutations. Using these complex data sets, and then proving benefits will require a combination of clinical trials and customer satisfaction. In addition, goal of AI implementation should move from a “Blackbox” mentality to an open innovation approach so that there is an open transparency leading to the best nutritional conclusions.

A third challenge to personalized nutrition is to provide the products and services at a price point that can be affordable to more than just early adopters with considerable expendable income. Low cost digital solutions for personal coaching like Noom can attract users but ultimately still require the customer to do most of the product acquisition work. Food delivery companies can provide quasi personalized nutrition but have scalability and freshness challenges. Companies that combine testing and then digital solutions like DayTwo provide true personalization, but pricing for single testing in the hundreds of dollars can be barrier and once again require the customer to pick and choose their nutritional solutions that match their profile. Pricing personalization can be tricky like in the case of Arivale which provided a large battery of tests plus personal coaching for a somewhat high consumer price but the level of service at even at that price proved to be an unsustainable business model. Panaceutics manufacturing platform is designed to produce a personalized product for roughly $3/pouch depending on ingredients. This is the price of a latte at your favorite coffee shop and less than the cost of the unhealthy cheeseburger at a fast food establishment.

For personalized nutrition manufacturing to provide a trusted safe product for each individual, companies must have robust Good Manufacturing Practices (GMP) in accordance with the established governmental regulations. These GMP practices need also to be innovative to be able to handle the variable multiple batch production needed as opposed to the traditional manufacturing GMPs that are for large scale production with very little variation between batches which maximizes the economies of scale. Panaceutics GMP manufacturing platform utilizes a combination of preprocess certification, in process, and post processing monitoring to verify proper production of each order. The automation provides software safeguards against operators making the wrong order by using QR codes for all ingredient inputs and order outputs. A cleaning in place (CIP) process has been built in to run between unique batches and clean validation techniques have also been established. Finally, the regulatory bodies like the FDA need to embrace and help provide constructive guidance to personalized manufacturing to allow for creative new products.
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