

## President's Message

Forrest Blocker, PhD



It has been an interesting summer for those of us involved in Healthcare, Biotech, and the Pharmaceutical Industry. I like to think about California as the Old Wild West. In these economic times it seems even more so. Boom or Bust. Now is the time to get out your six-gun—I mean that figuratively of course—and go into the Saloon for a little Buzz. Back in Washington, things move more slowly. Right now the issue is Healthcare Reform.

There are 50 million uninsured Americans. So who wouldn't want to get all these uninsured Americans access to healthcare? Anyone on the no-side of this argument will justify the position based on money. And it can be a compelling argument. Healthcare is expensive, really expensive in the United States, and getting more expensive. Why is it expensive?

One reason healthcare is expensive is that research is expensive. As we in AMWA know particularly, it is very expensive to innovate new drugs. The US leads the world in innovation. This is particularly important now that new biologics and targeted biologics are being developed both as a result of scientific discovery and to fill the pipeline void. But the cost translates to healthcare cost.

Central to the issue of enacting law is the issue of the relationship between the Pharmaceutical Industry and Congress. And the Pharmaceutical industry is heavily involved in congressional lobbying to protect their interests. Since 2008, health insurers, pharmaceuticals, and HMOs have contributed over \$500 million to federal candidates and parties. The solution to this is not easy and Congress is having a hard

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time dealing with it. One solution presented by John Kerry is to tax health insurance companies. We will all have to wait to see how that pans out.

Meanwhile, the US economy has lost 6.5 million jobs since December 2007. In fact, since June 2008, 98% of the largest labor markets lost jobs, according to the U.S. Bureau of Labor Statistics last week. California was an especially big loser, true to Wild West boom and bust tradition. The Los Angeles area has lost 259,100 jobs, the Bay Area 96,800 jobs, and Riverside 76,300 jobs since June 2008. And according to Bloomberg News last week, consumer confidence was projected to drop to 49, as compared to 58 last year. So it seems that the number of uninsured Americans will rise even higher.

Fortunately, the president of the Federal Reserve Bank of New York last week projected that the U.S. economy will see moderate growth in the second half of 2009 and consumer spending is likely to grow, albeit slowly. Let's hope this translates into jobs and let's hope that we, as a nation, figure out how to provide health care to everyone.

If you are in the job market, or just want to keep on your toes, I encourage you to attend AMWA's 69th Annual Conference in Dallas from October 22—24. In addition to the networking opportunities, attendance at the national conference offers a certificate program, wherein credited courses are offered. Descriptions of all AMWA-approved credit workshops can be found at the AMWA website.

### PCC 2010 Keynote Speakers, Registration Announced

The Pacific Coast Conference 2010 planning committee is very excited to announce our double keynote plenary session.

Best-selling author Mark Plotkin, Ph.D. (cofounder and current President of the Amazon Conservation Team, ACT) and Robert Urban, Ph.D (Executive Director, Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology) will join us at Asilomar in April 2010 to speak about subjects that are near and dear to them. Their presentations will be of great interest to us medical writers as well! Registration for the conference opens Dec. 10. Stay tuned for details!

### **Dr. Robert Urban presents: “Building the Future of Cancer Research at MIT”**

The David H. Koch Institute for Integrative Cancer Research was announced on October 9, 2007. By combining the faculty of what was then the MIT Center for Cancer Research (CCR) with an equivalent number of distinguished engineers drawn from various MIT departments, the Koch Institute continues CCR’s tradition of scientific excellence while also seeking to directly promote innovative ways to diagnose, monitor, and treat cancer through advanced technology.

Although the Koch Institutes does not directly provide clinical care for cancer patients, discoveries made by Koch Institute scientists and engineers, in collaboration with practicing physicians, are making an important impact on how disease is detected and managed in investigational settings.

Dr. Urban’s presentation will review the history leading up to the launch of the Koch Institute and provide current examples of research being conducted to deliver new oncology solutions, including nanotherapeutics, detection & monitoring, metastasis, personalized medicine, and tumor immunology.

### **Mark Plotkin presents: “Indigenous Plants, Conservation, and Medicine”**

For over 30 years, ethnobotanist Mark Plotkin, Ph.D., has searched the Amazon region for healing plants that may be sources of pharmaceuticals. In *The Shaman’s Apprentice* (1993), he described his early training with ethnobotany founder Richard Schultes and described some of his own pioneering work with indigenous healers.

By the early 1990s, Dr. Plotkin had catalogued more than 300 plants used by Amazonian shamans to treat viruses, skin disease, cough, and diabetes. *The Killers Within* (2002) focused on the threats posed by drug-resistant bacteria, the lack of drugs for and research into drug-resistant bacteria, and the need to explore both botanical and animal sources for potentially effective drugs.

Plotkin has worked to preserve indigenous cultures and their knowledge of healing plants and to promote ecological awareness and preservation of the rapidly dwindling Amazon forests. Part of this effort has been to foster a collaborative, mutually beneficial relationship (rather than the traditional one-sided exploitation) between pharmaceutical companies and the often poor and under-served countries and regions that are the source for many modern medications.

### **Educational Options for Breaking into Regulatory Medical Writing**

Mitch Gordon

I’ve seen the following question asked fairly often on the medical writing forums: What kind of certificate or degree can I earn that will make me more employable?

Writers, both new and experienced in another niche, are particularly interested now in regulatory writing. This is the kind of writing that drug or medical device companies use to apply for FDA approval of their products. It is the most lucrative and sought-after branch of medical writing. It is also difficult to break into.

Employers expect regulatory writers to know clinical trial processes thoroughly. They also expect writers to have detailed experience creating the documents that go into regulatory submissions. Deadlines are tight and mistakes are costly in the drug and device industries, so there is little tolerance or support for inexperienced writers. It’s not a setting where there are many opportunities to learn on the job.

Writers who want to work in the regulatory arena need to acquire the necessary knowledge somehow, of course. It’s natural that they would consider educational programs that will help qualify them for regulatory writing. And in recent years, the number of educational programs related to regulatory and clinical affairs has been steadily growing.

These programs educate not only writers, but many other professionals as well. Chemists, engineers, managers, biologists, and physicians need strong regulatory knowledge and credentials to establish themselves or advance in industry.

What kinds of programs are available? What do they cost? How long does it take to complete them? Are some credentials stronger than others in the eyes of employers and are the stronger ones worth the extra cost?

I can’t answer all of these questions definitively—you will have to do your own research.

However, I can give you a general idea of what’s out there. Most clinical and regulatory credential programs fall into

three categories: (1) certificates offered by professional associations, (2) certificates through university extension, and (3) advanced degrees. Here are my thoughts on each of these categories.

#### **Professional organization certificates**

You can earn certificates related to regulatory and clinical affairs through the American Medical Writers Association (AMWA), Regulatory Affairs Professionals Society (RAPS), or the Drug Information Association (DIA).

AMWA offers a Core Certificate in medical communications. It consists of 12 hours of general courses and 12 hours of specialty area classes, the latter of which can be on subjects related to pharmaceuticals. Additional coursework can be applied to an Advanced Certificate.

The benefits of the AMWA certificates are that they are specific to medical writing, cover useful topics, and can be combined with networking at AMWA conferences. Those who want to transition into regulatory writing can use these courses to strengthen their other credentials. The downside is that they provide fairly limited knowledge of regulatory and clinical affairs, and may be perceived as weak credentials when compared with more targeted certificates and degrees.

The DIA offers a Clinical Research Certificate that requires 41 hours of coursework, primarily at 1- to 2-day training sessions, but also online for some courses. Their classes can be costly, especially when you factor in travel, but taking them is a fairly quick way to acquire a certificate that indicates an understanding of clinical trials.

RAPS offers the Regulatory Affairs Certificate (RAC), which is considered a strong credential in the biopharmaceutical and medical device industries. It is awarded based on an examination, so you do not necessarily need to take RAPS courses. One approach is to complete a Masters degree or university extension certificate in regulatory affairs, and then sit for the RAC exam. Note that there are other requirements for the RAC, such as working time in industry, so contact RAPS for specifics.

#### **University extension program certificates**

Several universities offer certificates in regulatory affairs or clinical research through their extension departments. These accredited programs are exclusively online, exclusively onsite, or, in some cases, you can choose between those options. If you are in a metropolitan area with an established biomedical industry, one of your local universities may offer this kind of program. Otherwise, an online program is a good

option. There may be some entrance requirements, but these are less extensive than for degree programs and the program can be completed in considerably less time than a masters degree. I've seen some programs requiring as few as 12 units of coursework, and others requiring twice that, so do the research to find out what's best for you. Some institutions worth checking are the University of Georgia, University of Washington, and the University of California at Santa Cruz (regulatory and clinical) and at Berkeley (clinical only).

#### **Masters degree programs**

A handful of universities offer a Masters of Science in Regulatory Affairs, including San Diego State, Johns Hopkins, University of Washington, and University of Southern California. One school, University of the Sciences in Philadelphia, even has a masters program in Biomedical Writing.

Several of these universities offer certificates as well as degrees, and the certificate classes will typically contribute towards the masters if you choose to continue in the program. Some of these programs are either exclusively online (San Diego State and USC), or they're offered both online and onsite (Johns Hopkins).

Since you may have taken online courses in the past that failed to impress you, you may wonder how good an education you'll get if you pursue a masters degree online.

I can only speak from my own experience in the masters program at San Diego State (where I'm about a year away from completing my regulatory degree), but my answer is "pretty darned good."

While there is no face-to-face interaction, and the lectures are broadcast or downloaded, there is a great deal of communication with instructors and other students using email and the required discussion board participation. Most classes in my program require team projects where you collaborate with two or three students to develop a complex document like a regulatory strategic plan, a consent form, or a project schedule. It also helps that the instructors are mostly consultants from industry and the students all have

undergraduate degrees in the life sciences and, in many cases, plenty of industry experience.

So, is a certificate or a degree in regulatory affairs, clinical research, or biomedical writing right for you? It depends on your needs and circumstances. It takes a long time and considerable expense to complete one of these programs. Moreover, it can be hard to succeed with the training if you also have full-time job and/or family responsibilities. But at the end of the process, you have a strong credential that shows you understand this complex field. While this qualification alone may not pave the way to career success as a regulatory writer, it should help open the doors to the hands-on work experience you will also need.

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### **Coming in September: A Word Witch seminar led by Maggie Norris Advanced Features of Normal-dot-dot**

To a greater degree than many writers realize, “Normal-dot-dot” rules our working days.

Normal-dot-dot, also known as the “global template,” is the foundation of EVERY Word file. Some of the Word features that we love best and some of those we hate the most are built into the global template file (Normal.dot). Understanding the basics of the global template can help any writer to develop documents with a professional look and feel, and to troubleshoot annoying errors in their files. Being comfortable with some of its advanced features can improve the quality of our process (efficiency) and our product (more uniformity and fewer errors).

The Word Witch invites all AMWA members to Advanced Features of Normal-dot-dot, a seminar to explore some of the deeper functionality of the global template. After a review of basic techniques for building and managing documents using templates, we will look into some of the many uses of the Outline document view and building generated elements such as the Table of Contents.

#### **Advanced features of Normal-dot-dot, led by Maggie Norris of Fine Print Publication Services LLC**

**When:** Sat, Sept. 26th from 10:30-2:00

**Where:** Michael’s at Shoreline, 2960 N Shoreline Blvd, Mountain View, CA  
94043-1357. Tel: (650) 962-1014

**Cost:** \$30 members/\$40 non-members, lunch included

**Info:** Email Catherine Magill

### **Our June 6 Meeting: The Center for Health Design**

Mimi Wessling

The Center for Health Design has a 20-year history of improving the quality of healthcare through improving the design of the built environment. The “built environment” comprises the design of structures and surroundings and how they affect human activities. In this case, it describes the way that design of a hospital impedes or enhances the activities of healthcare professionals in their contacts with patients and those who accompany them.

This entails exploring how architecture and behavior work together, applying best practices and documenting things that go wrong, recognizing that, in effect, design becomes prescriptive. Evidence-based design (EBD) is particularly well-suited to healthcare because of the plethora of measurable outcomes that can be used to assure the best possible outcomes for the patient, the family, and the hospital staff.

#### **Why evidence-based design is increasingly important**

Natalie Zensius, the Center’s Director of Marketing and Communications, emphasized that EBD is not just a marketing tool. There is a business and financial imperative to truly improve safety and quality—the first of three internal revolutions in health care that have accelerated interest in EBD.

First, the quality and safety revolution. There is ample evidence of a measurable effect of the built environment on quality and safety. Interest in EBD is on the upswing: between 2003 and 2008, about 1200 studies have been published (available for download on the Center Web site).

Second, the current system of health care is based on an acute awareness of errors and attempts to avoid the costs errors impose on finances, the struggle to avoid losing staff, and the human costs accrued by medical errors.

Third, reimbursement has shifted from resources consumed to outcomes achieved. Since many US hospitals are at the end of their useful lives, there is much new construction going on. In short, EBD is a way to apply lessons learned through research to hospitals while they are being built.

### **Pebbles: ripples in the healthcare water**

To date, 65 hospitals in the United States and abroad have become involved in the Center's "Pebble Project." For the patient, this means keeping close records of environmental noise, looking at factors that affect distribution of medical care, pain levels among patients, distribution of medications; and for the hospital workers, looking for possible safety hazards. In short, looking for the gaps and seeing how they might be filled.

Pebble Project members and Center staff not only look at literature and research to see where the evidence lies for using certain design features. They take the further step to see if the hypothesized outcomes are borne out by reality. This is heart of the evidence-based design process, and ultimately what the Pebble Project is all about.

#### **The evidence for evidence-based design**

Amy Keller, an architect and Research Associate at the Center and its Pebble Design Strategist, described seven categories of evidence, starting with goals and ending with a measure of how outcomes are affected.

First comes patient safety, designing strategies that reduce medication errors. Amy cited a hospital in Michigan that built only single rooms and found an 11% decrease in medication errors. This Pebble Project hospital is now looking at the newborn ICU (NICU) environment, examining, for instance, the effect of decentralizing nursing stations. Early findings indicate that nurses walk up to a mile less during charting activities.

In an Indiana Pebble (as they refer to Project member hospitals), the notion of "acutely adaptable" rooms is being tested. Crucial physiological indicators are constantly read for evidence that the patient needs to be transferred to the ICU, with the goal of reducing unnecessary transfers that can be the source of errors.

Another important spatial modification being tested is the decentralized nursing station. No longer is there a single nursing station located at the end of a hall, but several smaller stations located near patient rooms. While this arrangement seems more comfortable for patients, Amy emphasized the interaction between the built and cultural environments. This arrangement means that patients and nurses can interact more naturally. It also puts the onus on nurses to interact with each other.

The second category of evidence follows from the first: worker safety. This involves lighting choices, location of staff, and relieving staff of

physical stressors. In a pilot study for an Oregon replacement hospital, ceiling lifts were installed in the existing neurological and ICU units. Patients could be taken to the toilet room or to a wheelchair by these lifts, reducing patient-handling injuries by 83%. In the new hospital, the added expense of installing the lifts will be recovered in two to five years by reduced worker compensation costs.

Rather than expanding the length of this article unduly, I'll summarize the remaining categories of research and direct you to the Center's Web site for details. Building in response to the climate and possible climate change requires careful consideration of materials. Improving staff effectiveness, quality of care, and overall cost effectiveness are dependent on the final category of research, documenting the evidence-based design process itself. The Pebbles and other participating organizations are building a knowledge base that will be used to understand the effectiveness of the individual efforts that go into evidence-based design.

Just a few more details on EBD: Not all EBD issues are easy to solve. For all the attractive features of the decentralized nursing station notion, it's not simple to harmonize location for patient service and for staff communication. Second, the EBD outreach is not just to well-capitalized private hospitals in urban locations. It also embraces rural hospitals that struggle financially and long term care facilities.

The Center's effectiveness is enhanced by its advocates: people in healthcare who believe in the EBD effort, staff and Board members who present its work at conferences (and meetings like ours); and volunteers who send research results out to industry in an outreach effort.

#### **Looking to the future**

The Center has developed a home-grown educational project to spread EBD across the healthcare industry. Financed by the Robert Wood Johnson Foundation, they have spent countless hours developing study materials for an exam aimed at educating the healthcare community about EBD. The Evidence-Based Design Accreditation and Certification (EDAC)

currently has 130 applicants in 35 countries signed up to take the test who are already putting these principles into practice.

## RECEIVE \$25 GIFT CARDS

That's right, \$25. It's not a typo!

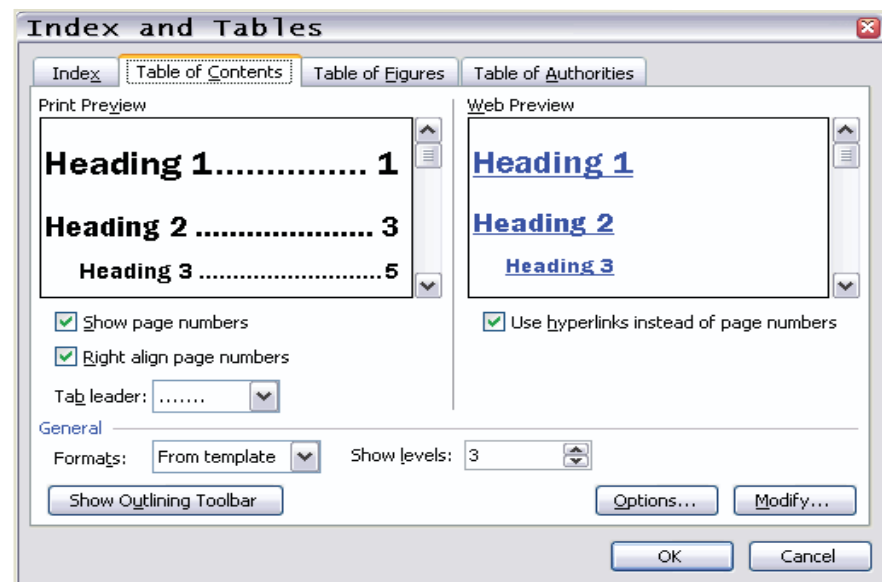
AMWA is giving away \$25 gift cards from Amazon.com to every AMWA member who successfully recruits a new member in 2009. No drawing to enter, no waiting—just successfully recruit a new member by December 31, 2009, and the gift card is yours. And there is no limit to the number of gift cards you can receive!

More detailed information and a form are available on our Web site.

## The Word Witch: Custom formatting for a generated TOC

Maggie Norris

A good sturdy template, applied consistently, is a necessity for developing quality documents with Microsoft Word. Among the most useful features enabled by consistent application of the template is the Table of Contents. This feature generates a cross-referenced TOC, with heading text and page numbers. The generated TOC feature will be discussed in detail at the next Word Witch seminar on Sept. 26. Meanwhile, here is a brief tutorial on one important aspect of the TOC: controlling the formatting of the TOC entries.



The tools that control the TOC display options are located in the Table of Contents tab of the Index and Tables dialog box. One of those tools gives the user access to the paragraph formatting options for the individual TOC levels. Use this tool to customize formatting for each level in the generated TOC.

### Tutorial: Customizing TOC styles

Work in a copy of a complex document with multiple heading levels. If the file contains a generated TOC, delete it.

With the insertion point where you want the TOC to begin, navigate to the Table of Contents tab: in Word 2003, choose **Insert | Reference | Index and Tables | Table of Contents | OK**; in Word 2004 (Mac), choose **Insert | Index and Tables | Table of Contents | OK**. The TOC magically appear behind your cursor. Now reopen the tab and take a close look at its components.

### Print Preview pane

The layout of the tab is slightly different in the Win and Mac versions. In Word 2003, the tab is divided into two panes: **Print Preview** (left) and **Web Preview** (right). Ignore the right pane for now.

The **Print Preview** pane displays a model of the TOC formatting, with dummy heading text ("Heading 1," "Heading 2"), right-aligned page numbers, and a tab leader. Clear and reactivate each of the checkboxes below Print Preview and choose different options in the Tab leader dropdown list to observe the effects in **Print Preview**.

### TOC Style dialog box

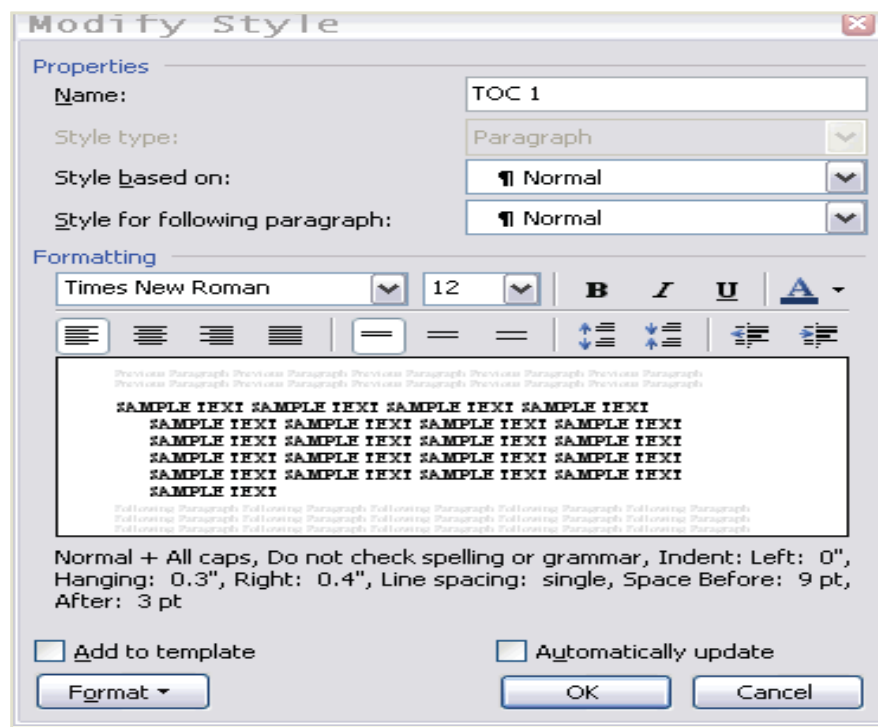
Now click **Modify** to call up a special version of the **Style** dialog box. Look at the **Styles** list for a minute and something important becomes clear: each TOC style is a paragraph style. You can modify the formatting of the TOC styles the same way you modify any other paragraph style.

Select **TOC1** for a preview of the level 1 headings in the TOC.

### Modify Style dialog box

With TOC1 still selected, click **Modify** to call up a special version of the **Modify Style** dialog box. Make a simple and dramatic

change to the TOC1 paragraph style, eg, change the font color to red. Accept the change and go back to the Table of Contents tab. Observe the effect of the change in Print Preview. Click OK to insert a TOC in the file and close the dialog box. Observe the effects of the changed font color in the TOC itself.



Go back into the Modify Style dialog box and make other changes, eg, increase the Space before measurement for the TOC1 paragraph style. Observe the effects of each change in Print Preview, then regenerate the TOC (click OK) and observe the effects there, too.

Keep making changes until you feel comfortable modifying the TOC .

#### TOC tip

You could find yourself feeling like the sorcerer's apprentice if you combine a live TOC with Track Changes. The best way to avoid problems is to delete the TOC from a file before attempting to edit it.

In other words, don't work in a file while the generated TOC is live. Allow enough time just before the deadline to troubleshoot the document

structure and generate the TOC. Remember to turn off Track Changes.

#### See you at the seminar?

If you are planning to attend the Advanced Normal-dot-dot seminar and have specific template-related features you would like to discuss, please contact me at [Fine\\_Print\\_Services@mac.com](mailto:Fine_Print_Services@mac.com).

#### Like What You See?

#### Want to Make it Better?

*The Pacemaker*, our Northern California chapter newsletter, needs your help!

Please send your suggestions and submissions to *Pacemaker* editor Fred Gebhart, [pacemaker@amwancal.org](mailto:pacemaker@amwancal.org). The deadline for submissions to the next bimonthly issue, due out in Early October, is September 15, 2009.

#### 2009 Northern California Board of Directors

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